

# Postmarket Activities: Mandatory Reporting Requirements and Recalls, Corrections and Removals

Michelle Noonan  
International Policy Analyst  
Office of the Center Director  
Center for Devices and Radiological Health  
US Food and Drug Administration  
[michelle.noonan@fda.hhs.gov](mailto:michelle.noonan@fda.hhs.gov)

# Agenda

- Postmarket requirements
  - 21 CFR 820 – Quality System Regulation/Medical Device Good Manufacturing Practices
  - Medical Device Tracking
  - 522 Postmarket Surveillance Studies Program
  - Post-Approval Studies Program
  - **Mandatory Reporting Requirements**
  - **Recalls, Corrections and Removals**

# Postmarket Requirements

- Medical device manufacturers, and others involved in the distribution of devices, must follow certain requirements and regulations once devices are on the market
  - tracking systems
  - reporting of device malfunctions, serious injuries or deaths
  - registering the establishments where devices are produced or distributed

# Mandatory Reporting Requirements

- Section 519 of the Federal Food, Drug and Cosmetic Act describes the requirements for “Records and Reports on Devices”
  - *Every person who is a manufacturer or importer of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness.*
- [21 CFR Part 803](#), establishes the requirements for medical device reporting for mandatory reporting entities





# Who Must Report Adverse Events?

- The regulation provides a mechanism for FDA and manufacturers to identify and monitor significant adverse events involving marketed medical devices
- Those who must report are:
  - Manufacturers
  - User Facilities
  - Importers
  - Distributors

# Manufacturer

- Any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. This includes:
  - Domestic Manufacturers
  - Repackagers
  - Relabelers
  - Contract Manufacturers
  - Specification Developers
  - Foreign Manufacturers



© Can Stock Photo

# Importer

- Any person who imports a device into the United States and who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper or labeling of the device or device package.



# Distributor

- Any person (other than the manufacturer or importer) who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. If you repackage or otherwise change the container, wrapper, or labeling, you are considered a manufacturer as defined in this section.





# Device User Facility

- A hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility which is not a physician's office. School nurse offices and employee health units are not user facilities.



# Reporting Requirements

REPORTER	WHAT TO REPORT	WHERE	WHEN
Manufacturer (Mfr.)	Deaths, Serious Injuries, Malfunction	FDA	Within 30 calendar days
	Events that require remedial action to prevent an unreasonable risk of substantial harm	FDA	Within 5 working days
	Supplements (Follow-up Reports)	FDA	Within 30 calendar days
Importer	Deaths and Serious Injuries	FDA and Mfg	Within 30 calendar days
	Malfunctions	Mfg	Within 30 calendar days
User Facility	Deaths	FDA and Mfg	Within 10 calendar days
	Serious Injuries	Mfg	Within 10 calendar days
	Annual summary of death and serious injury reports	FDA	January 1 for the preceding year

# 5-day reports and Remedial Action

- A “remedial action” is any action, other than routine maintenance or servicing of a device, necessary to prevent recurrence of an MDR reportable event. FDA does not consider an action taken to correct only a single device involved in an MDR reportable event to be a remedial action.
- Not all MDR reportable events requiring remedial action need to be submitted as 5-day reports. Only events that require remedial actions to:
  - Prevent an unreasonable risk of substantial harm to the public health or
  - Events for which FDA requests such report must be submitted

# Reportability Determination



Device related  
complaint

MDR  
Reportability  
assessment

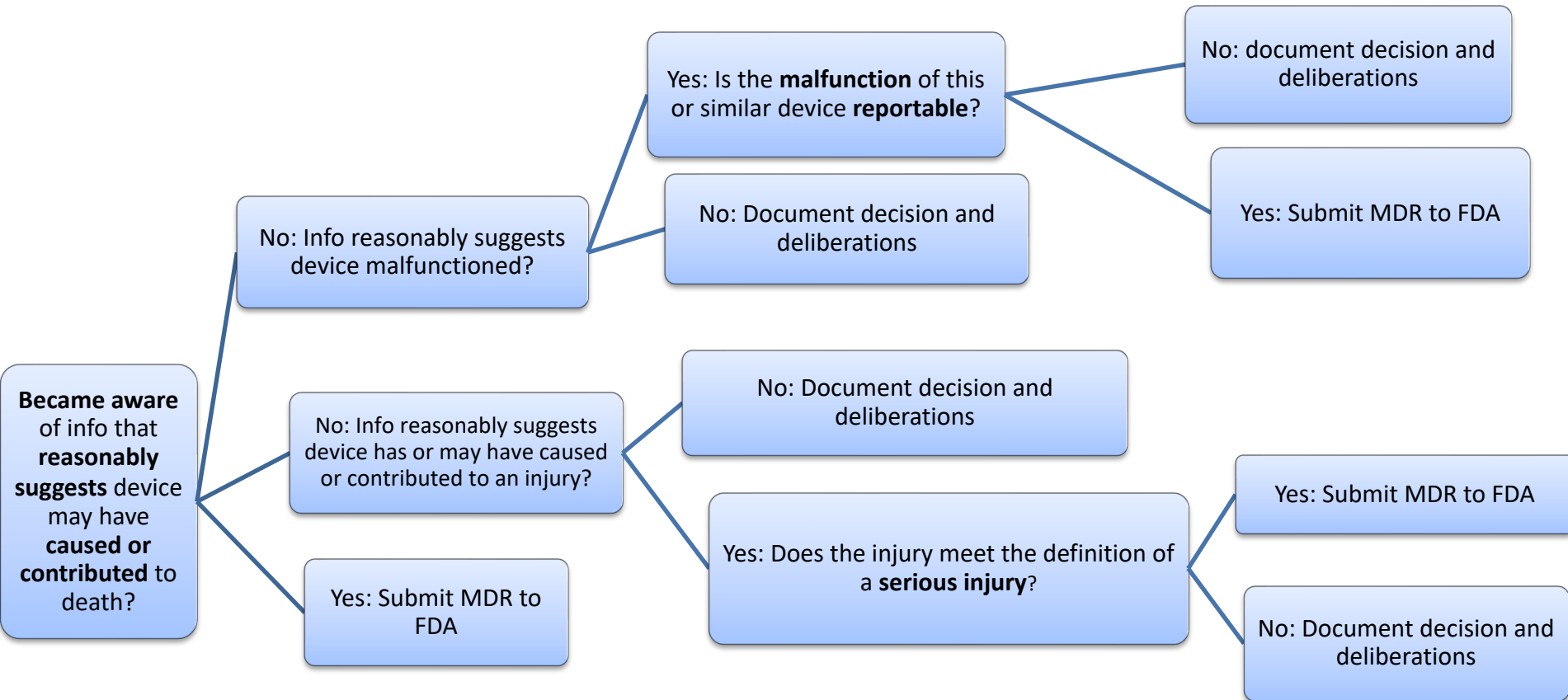
Report to FDA  
and  
recordkeeping

# Complaints

- What is a complaint?
  - Any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution
- Sources for potential complaints:
  - Service reports
  - Social media, publicly available articles, news
  - Scientific journals
  - Returned devices
  - Clinical investigations
- Review and evaluate all device-related complaints to determine whether the complaint represents an MDR reportable event



# Reportability Determination



**Start with a device-related complaint**

# Becoming Aware

- A firm becomes aware of an event whenever
  - Any of its employees become aware of information that reasonably suggests that an event is required to be reported in a 30-day report or in a 5-day report that we have requested from you; or
  - Any of its employees with management or supervisory responsibilities over persons with regulatory, scientific or technical responsibilities (including consultants and contractors) or whose duties relate to the collection and reporting of adverse events, become aware from any source that an MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.

# Reasonably Suggests

- Information that reasonably suggests can include:
  - Professional, scientific or medical facts and observations, trend analysis and opinions
- What if the information in the initial report does not reasonably suggest?
  - Then you have not yet become aware of a reportable event



# Caused or Contributed

- A death or serious injury was or may have been attributed to a medical device, or
- A medical device was or may have been a factor in a death or serious injury, including events resulting from:
  - Failure
  - Malfunction
  - Improper or inadequate design
  - Manufacture
  - Labeling
  - User error

# Serious Injury

- An injury or illness that is:
  - Life-threatening
  - Results in permanent impairment of a body function or permanent damage to a body structure
  - Necessitates medical or surgical intervention to preclude permanent impairment or damage to a body function or structure

# Reportable Malfunctions

- The malfunction would be likely to cause or contribute to a death or serious injury, if the malfunction of the same or similar device were to recur
- The malfunction results in the failure of the device to perform its essential function and compromises the device's therapeutic, monitoring, or diagnostic effectiveness, which could cause or contribute to a death or serious injury or other significant adverse device experience required by the regulation

# MDR Reportable Event

- An event that manufacturers or importers become aware of that reasonably suggests that one of their marketed devices:
  - May have caused or contributed to a death or serious injury, or
  - Has malfunctioned and that device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if it were to recur

# eMDR

- Since August 14, 2015, MDR reports must be submitted electronically by manufacturers and importers. User facilities are still allowed to submit paper MDRs using the FDA's Medwatch Form 3500A.
- Recordkeeping should include copies of all submitted reports and acknowledgements

U.S. Department of Health and Human Services  
**MEDWATCH**  
 Form FDA 3500A (10/15)

For use by user facilities, importers, distributors and health care providers for MANDATORY reporting  
 Page 1 of 3

Form Approved OMB No. 0910-0041, Previous Edition 03/09  
 See PDF instructions on page 3

UFI Report # \_\_\_\_\_  
 FDA Use Only

Notes: For details on the "Mandatory" status and categories, under which submission, and category for severity, see 21 CFR 312.62.

**A. PATIENT INFORMATION**

1. Patient Identifier:  Full  Age  Year of Birth  Sex  Weight  
 Patient ID  Medical Record #  Other  
 Other

2. Age:  Infant  Child  Adolescent  Adult  Elderly

3. Sex:  Male  Female

4. Weight:  None  40  45

5. Date: \_\_\_\_\_ Frequency: \_\_\_\_\_ Prior Count: \_\_\_\_\_

6. Therapy Date: If unknown, the earliest date to be treated for the condition

7. Exact Dates After Use:  Exact  Approx  Don't Know

8. Disposition:  Discontinued  Not Discontinued  Don't Know

9. Exact Dates After Reinstatement:  Exact  Approx  Don't Know

**B. GOVERNMENT EVENT OR PRODUCT PROBLEM**

1. Adverse Event:  Yes  No

2. Government Event:  Yes  No

3. Recall:  Yes  No

4. Date of the Report: \_\_\_\_\_

5. Record Count of Problem: \_\_\_\_\_

6. Relevant Test/Laboratory Data, including Date: \_\_\_\_\_

7. Other Relevant History, including Preexisting Medical Conditions, Allergies, Current and Past Medications, and Other Relevant Information: \_\_\_\_\_

**C. SUSPECT PRODUCT**

1. Name, Trade Name/Manufacturer, Strength: \_\_\_\_\_

2. Manufacturer/Company: \_\_\_\_\_

3. Name and Strength: \_\_\_\_\_

4. Manufacturer/Company: \_\_\_\_\_

5. Component Medical Products and Therapy Dates (Include treatment of wound): \_\_\_\_\_

6. Device available for evaluation?  Yes  No

7. Returned to Manufacturer:  Yes  No

8. Component Medical Products and Therapy Dates (Include treatment of wound): \_\_\_\_\_

**D. SUSPECT MEDICAL DEVICE**

1. Device Name: \_\_\_\_\_

2. Company Device Name: \_\_\_\_\_

3. Manufacturer Name, City and State: \_\_\_\_\_

4. Model #: \_\_\_\_\_ Lot #: \_\_\_\_\_

5. Operator of Device:  Patient  Health Care Provider

6. Catalog #: \_\_\_\_\_

7. Distribution Date (month/year): \_\_\_\_\_

8. Date of Report: \_\_\_\_\_

9. Date of Incident: \_\_\_\_\_

10. Date of Report: \_\_\_\_\_

11. Is this a single use device that was reprocessed and reused on a patient?  Yes  No

12. Is this a re-usable device that was reprocessed and reused on a patient?  Yes  No

13. The Name & Title Name and Address of Reporter: \_\_\_\_\_

**E. REPORTER**

1. Name and Address: \_\_\_\_\_

2. Title: \_\_\_\_\_

3. City: \_\_\_\_\_

4. State: \_\_\_\_\_

5. Country: \_\_\_\_\_

6. Phone #: \_\_\_\_\_

7. Email: \_\_\_\_\_

8. Report Type:  Adverse Event  Product Problem  Medical Device

9. Report Status:  New  Revised  Closed

10. Report Date: \_\_\_\_\_

11. Report Time: \_\_\_\_\_

12. Report Location: \_\_\_\_\_

13. Report Category: \_\_\_\_\_

14. Report Subcategory: \_\_\_\_\_

15. Report Severity: \_\_\_\_\_

16. Report Outcome: \_\_\_\_\_

17. Report Status: \_\_\_\_\_

18. Report Date: \_\_\_\_\_

19. Report Time: \_\_\_\_\_

20. Report Location: \_\_\_\_\_

21. Report Category: \_\_\_\_\_

22. Report Subcategory: \_\_\_\_\_

23. Report Severity: \_\_\_\_\_

24. Report Outcome: \_\_\_\_\_

25. Report Status: \_\_\_\_\_

26. Report Date: \_\_\_\_\_

27. Report Time: \_\_\_\_\_

28. Report Location: \_\_\_\_\_

29. Report Category: \_\_\_\_\_

30. Report Subcategory: \_\_\_\_\_

31. Report Severity: \_\_\_\_\_

32. Report Outcome: \_\_\_\_\_

33. Report Status: \_\_\_\_\_

34. Report Date: \_\_\_\_\_

35. Report Time: \_\_\_\_\_

36. Report Location: \_\_\_\_\_

37. Report Category: \_\_\_\_\_

38. Report Subcategory: \_\_\_\_\_

39. Report Severity: \_\_\_\_\_

40. Report Outcome: \_\_\_\_\_

41. Report Status: \_\_\_\_\_

42. Report Date: \_\_\_\_\_

43. Report Time: \_\_\_\_\_

44. Report Location: \_\_\_\_\_

45. Report Category: \_\_\_\_\_

46. Report Subcategory: \_\_\_\_\_

47. Report Severity: \_\_\_\_\_

48. Report Outcome: \_\_\_\_\_

49. Report Status: \_\_\_\_\_

50. Report Date: \_\_\_\_\_

51. Report Time: \_\_\_\_\_

52. Report Location: \_\_\_\_\_

53. Report Category: \_\_\_\_\_

54. Report Subcategory: \_\_\_\_\_

55. Report Severity: \_\_\_\_\_

56. Report Outcome: \_\_\_\_\_

57. Report Status: \_\_\_\_\_

58. Report Date: \_\_\_\_\_

59. Report Time: \_\_\_\_\_

60. Report Location: \_\_\_\_\_

61. Report Category: \_\_\_\_\_

62. Report Subcategory: \_\_\_\_\_

63. Report Severity: \_\_\_\_\_

64. Report Outcome: \_\_\_\_\_

65. Report Status: \_\_\_\_\_

66. Report Date: \_\_\_\_\_

67. Report Time: \_\_\_\_\_

68. Report Location: \_\_\_\_\_

69. Report Category: \_\_\_\_\_

70. Report Subcategory: \_\_\_\_\_

71. Report Severity: \_\_\_\_\_

72. Report Outcome: \_\_\_\_\_

73. Report Status: \_\_\_\_\_

74. Report Date: \_\_\_\_\_

75. Report Time: \_\_\_\_\_

76. Report Location: \_\_\_\_\_

77. Report Category: \_\_\_\_\_

78. Report Subcategory: \_\_\_\_\_

79. Report Severity: \_\_\_\_\_

80. Report Outcome: \_\_\_\_\_

81. Report Status: \_\_\_\_\_

82. Report Date: \_\_\_\_\_

83. Report Time: \_\_\_\_\_

84. Report Location: \_\_\_\_\_

85. Report Category: \_\_\_\_\_

86. Report Subcategory: \_\_\_\_\_

87. Report Severity: \_\_\_\_\_

88. Report Outcome: \_\_\_\_\_

89. Report Status: \_\_\_\_\_

90. Report Date: \_\_\_\_\_

91. Report Time: \_\_\_\_\_

92. Report Location: \_\_\_\_\_

93. Report Category: \_\_\_\_\_

94. Report Subcategory: \_\_\_\_\_

95. Report Severity: \_\_\_\_\_

96. Report Outcome: \_\_\_\_\_

97. Report Status: \_\_\_\_\_

98. Report Date: \_\_\_\_\_

99. Report Time: \_\_\_\_\_

100. Report Location: \_\_\_\_\_

101. Report Category: \_\_\_\_\_

102. Report Subcategory: \_\_\_\_\_

103. Report Severity: \_\_\_\_\_

104. Report Outcome: \_\_\_\_\_

105. Report Status: \_\_\_\_\_

106. Report Date: \_\_\_\_\_

107. Report Time: \_\_\_\_\_

108. Report Location: \_\_\_\_\_

109. Report Category: \_\_\_\_\_

110. Report Subcategory: \_\_\_\_\_

111. Report Severity: \_\_\_\_\_

112. Report Outcome: \_\_\_\_\_

113. Report Status: \_\_\_\_\_

114. Report Date: \_\_\_\_\_

115. Report Time: \_\_\_\_\_

116. Report Location: \_\_\_\_\_

117. Report Category: \_\_\_\_\_

118. Report Subcategory: \_\_\_\_\_

119. Report Severity: \_\_\_\_\_

120. Report Outcome: \_\_\_\_\_

121. Report Status: \_\_\_\_\_

122. Report Date: \_\_\_\_\_

123. Report Time: \_\_\_\_\_

124. Report Location: \_\_\_\_\_

125. Report Category: \_\_\_\_\_

126. Report Subcategory: \_\_\_\_\_

127. Report Severity: \_\_\_\_\_

128. Report Outcome: \_\_\_\_\_

129. Report Status: \_\_\_\_\_

130. Report Date: \_\_\_\_\_

131. Report Time: \_\_\_\_\_

132. Report Location: \_\_\_\_\_

133. Report Category: \_\_\_\_\_

134. Report Subcategory: \_\_\_\_\_

135. Report Severity: \_\_\_\_\_

136. Report Outcome: \_\_\_\_\_

137. Report Status: \_\_\_\_\_

138. Report Date: \_\_\_\_\_

139. Report Time: \_\_\_\_\_

140. Report Location: \_\_\_\_\_

141. Report Category: \_\_\_\_\_

142. Report Subcategory: \_\_\_\_\_

143. Report Severity: \_\_\_\_\_

144. Report Outcome: \_\_\_\_\_

145. Report Status: \_\_\_\_\_

146. Report Date: \_\_\_\_\_

147. Report Time: \_\_\_\_\_

148. Report Location: \_\_\_\_\_

149. Report Category: \_\_\_\_\_

150. Report Subcategory: \_\_\_\_\_

151. Report Severity: \_\_\_\_\_

152. Report Outcome: \_\_\_\_\_

153. Report Status: \_\_\_\_\_

154. Report Date: \_\_\_\_\_

155. Report Time: \_\_\_\_\_

156. Report Location: \_\_\_\_\_

157. Report Category: \_\_\_\_\_

158. Report Subcategory: \_\_\_\_\_

159. Report Severity: \_\_\_\_\_

160. Report Outcome: \_\_\_\_\_

161. Report Status: \_\_\_\_\_

162. Report Date: \_\_\_\_\_

163. Report Time: \_\_\_\_\_

164. Report Location: \_\_\_\_\_

165. Report Category: \_\_\_\_\_

166. Report Subcategory: \_\_\_\_\_

167. Report Severity: \_\_\_\_\_

168. Report Outcome: \_\_\_\_\_

169. Report Status: \_\_\_\_\_

170. Report Date: \_\_\_\_\_

171. Report Time: \_\_\_\_\_

172. Report Location: \_\_\_\_\_

173. Report Category: \_\_\_\_\_

174. Report Subcategory: \_\_\_\_\_

175. Report Severity: \_\_\_\_\_

176. Report Outcome: \_\_\_\_\_

177. Report Status: \_\_\_\_\_

178. Report Date: \_\_\_\_\_

179. Report Time: \_\_\_\_\_

180. Report Location: \_\_\_\_\_

181. Report Category: \_\_\_\_\_

182. Report Subcategory: \_\_\_\_\_

183. Report Severity: \_\_\_\_\_

184. Report Outcome: \_\_\_\_\_

185. Report Status: \_\_\_\_\_

186. Report Date: \_\_\_\_\_

187. Report Time: \_\_\_\_\_

188. Report Location: \_\_\_\_\_

189. Report Category: \_\_\_\_\_

190. Report Subcategory: \_\_\_\_\_

191. Report Severity: \_\_\_\_\_

192. Report Outcome: \_\_\_\_\_

193. Report Status: \_\_\_\_\_

194. Report Date: \_\_\_\_\_

195. Report Time: \_\_\_\_\_

196. Report Location: \_\_\_\_\_

197. Report Category: \_\_\_\_\_

198. Report Subcategory: \_\_\_\_\_

199. Report Severity: \_\_\_\_\_

200. Report Outcome: \_\_\_\_\_

201. Report Status: \_\_\_\_\_

202. Report Date: \_\_\_\_\_

203. Report Time: \_\_\_\_\_

204. Report Location: \_\_\_\_\_

205. Report Category: \_\_\_\_\_

206. Report Subcategory: \_\_\_\_\_

207. Report Severity: \_\_\_\_\_

208. Report Outcome: \_\_\_\_\_

209. Report Status: \_\_\_\_\_

210. Report Date: \_\_\_\_\_

211. Report Time: \_\_\_\_\_

212. Report Location: \_\_\_\_\_

213. Report Category: \_\_\_\_\_

214. Report Subcategory: \_\_\_\_\_

215. Report Severity: \_\_\_\_\_

216. Report Outcome: \_\_\_\_\_

217. Report Status: \_\_\_\_\_

218. Report Date: \_\_\_\_\_

219. Report Time: \_\_\_\_\_

220. Report Location: \_\_\_\_\_

221. Report Category: \_\_\_\_\_

222. Report Subcategory: \_\_\_\_\_

223. Report Severity: \_\_\_\_\_

224. Report Outcome: \_\_\_\_\_

225. Report Status: \_\_\_\_\_

226. Report Date: \_\_\_\_\_

227. Report Time: \_\_\_\_\_

228. Report Location: \_\_\_\_\_

229. Report Category: \_\_\_\_\_

230. Report Subcategory: \_\_\_\_\_

231. Report Severity: \_\_\_\_\_

232. Report Outcome: \_\_\_\_\_

233. Report Status: \_\_\_\_\_

234. Report Date: \_\_\_\_\_

235. Report Time: \_\_\_\_\_

236. Report Location: \_\_\_\_\_

237. Report Category: \_\_\_\_\_

238. Report Subcategory: \_\_\_\_\_

239. Report Severity: \_\_\_\_\_

240. Report Outcome: \_\_\_\_\_

241. Report Status: \_\_\_\_\_

242. Report Date: \_\_\_\_\_

243. Report Time: \_\_\_\_\_

244. Report Location: \_\_\_\_\_

245. Report Category: \_\_\_\_\_

246. Report Subcategory: \_\_\_\_\_

247. Report Severity: \_\_\_\_\_

248. Report Outcome: \_\_\_\_\_

249. Report Status: \_\_\_\_\_

250. Report Date: \_\_\_\_\_

251. Report Time: \_\_\_\_\_

252. Report Location: \_\_\_\_\_

253. Report Category: \_\_\_\_\_

254. Report Subcategory: \_\_\_\_\_

255. Report Severity: \_\_\_\_\_

256. Report Outcome: \_\_\_\_\_

257. Report Status: \_\_\_\_\_

258. Report Date: \_\_\_\_\_

259. Report Time: \_\_\_\_\_

260. Report Location: \_\_\_\_\_

261. Report Category: \_\_\_\_\_

262. Report Subcategory: \_\_\_\_\_

263. Report Severity: \_\_\_\_\_

264. Report Outcome: \_\_\_\_\_

265. Report Status: \_\_\_\_\_

266. Report Date: \_\_\_\_\_

267. Report Time: \_\_\_\_\_

268. Report Location: \_\_\_\_\_

269. Report Category: \_\_\_\_\_

270. Report Subcategory: \_\_\_\_\_

271. Report Severity: \_\_\_\_\_

272. Report Outcome: \_\_\_\_\_

273. Report Status: \_\_\_\_\_

274. Report Date: \_\_\_\_\_

275. Report Time: \_\_\_\_\_

276. Report Location: \_\_\_\_\_

277. Report Category: \_\_\_\_\_

278. Report Subcategory: \_\_\_\_\_

279. Report Severity: \_\_\_\_\_

280. Report Outcome: \_\_\_\_\_

281. Report Status: \_\_\_\_\_

282. Report Date: \_\_\_\_\_

283. Report Time: \_\_\_\_\_

284. Report Location: \_\_\_\_\_

285. Report Category: \_\_\_\_\_

286. Report Subcategory: \_\_\_\_\_

287. Report Severity: \_\_\_\_\_

288. Report Outcome: \_\_\_\_\_

289. Report Status: \_\_\_\_\_

290. Report Date: \_\_\_\_\_

291. Report Time: \_\_\_\_\_

292. Report Location: \_\_\_\_\_

293. Report Category: \_\_\_\_\_

294. Report Subcategory: \_\_\_\_\_

295. Report Severity: \_\_\_\_\_

296. Report Outcome: \_\_\_\_\_

297. Report Status: \_\_\_\_\_

298. Report Date: \_\_\_\_\_

299. Report Time: \_\_\_\_\_

300. Report Location: \_\_\_\_\_

301. Report Category: \_\_\_\_\_

302. Report Subcategory: \_\_\_\_\_

303. Report Severity: \_\_\_\_\_

304. Report Outcome: \_\_\_\_\_

305. Report Status: \_\_\_\_\_

306. Report Date: \_\_\_\_\_

307. Report Time: \_\_\_\_\_

308. Report Location: \_\_\_\_\_

309. Report Category: \_\_\_\_\_

310. Report Subcategory: \_\_\_\_\_

311. Report Severity: \_\_\_\_\_

312. Report Outcome: \_\_\_\_\_

313. Report Status: \_\_\_\_\_

314. Report Date: \_\_\_\_\_

315. Report Time: \_\_\_\_\_

316. Report Location: \_\_\_\_\_

317. Report Category: \_\_\_\_\_

318. Report Subcategory: \_\_\_\_\_

319. Report Severity: \_\_\_\_\_

320. Report Outcome: \_\_\_\_\_

321. Report Status: \_\_\_\_\_

322. Report Date: \_\_\_\_\_

323. Report Time: \_\_\_\_\_

324. Report Location: \_\_\_\_\_

325. Report Category: \_\_\_\_\_

326. Report Subcategory: \_\_\_\_\_

327. Report Severity: \_\_\_\_\_

328. Report Outcome: \_\_\_\_\_

329. Report Status: \_\_\_\_\_

330. Report Date: \_\_\_\_\_

331. Report Time: \_\_\_\_\_

332. Report Location: \_\_\_\_\_

333. Report Category: \_\_\_\_\_

334. Report Subcategory: \_\_\_\_\_

335. Report Severity: \_\_\_\_\_

336. Report Outcome: \_\_\_\_\_

337. Report Status: \_\_\_\_\_

338. Report Date: \_\_\_\_\_

339. Report Time: \_\_\_\_\_

340. Report Location: \_\_\_\_\_

341. Report Category: \_\_\_\_\_

342. Report Subcategory: \_\_\_\_\_

343. Report Severity: \_\_\_\_\_

344. Report Outcome: \_\_\_\_\_

345. Report Status: \_\_\_\_\_

346. Report Date: \_\_\_\_\_

347. Report Time: \_\_\_\_\_

348. Report Location: \_\_\_\_\_

349. Report Category: \_\_\_\_\_

350. Report Subcategory: \_\_\_\_\_

351. Report Severity: \_\_\_\_\_

352. Report Outcome: \_\_\_\_\_

353. Report Status: \_\_\_\_\_

354. Report Date: \_\_\_\_\_

355. Report Time: \_\_\_\_\_

356. Report Location: \_\_\_\_\_

357. Report Category: \_\_\_\_\_

358. Report Subcategory: \_\_\_\_\_

359. Report Severity: \_\_\_\_\_

360. Report Outcome: \_\_\_\_\_

361. Report Status: \_\_\_\_\_

362. Report Date: \_\_\_\_\_

363. Report Time: \_\_\_\_\_

364. Report Location: \_\_\_\_\_

365. Report Category: \_\_\_\_\_

366. Report Subcategory: \_\_\_\_\_

367. Report Severity: \_\_\_\_\_

368. Report Outcome: \_\_\_\_\_

369. Report Status: \_\_\_\_\_

370. Report Date: \_\_\_\_\_

371. Report Time: \_\_\_\_\_

372. Report Location: \_\_\_\_\_

373. Report Category: \_\_\_\_\_

374. Report Subcategory: \_\_\_\_\_

375. Report Severity: \_\_\_\_\_

376. Report Outcome: \_\_\_\_\_

377. Report Status: \_\_\_\_\_

378. Report Date: \_\_\_\_\_

379. Report Time: \_\_\_\_\_

380. Report Location: \_\_\_\_\_

381. Report Category: \_\_\_\_\_

382. Report Subcategory: \_\_\_\_\_

383. Report Severity: \_\_\_\_\_

384. Report Outcome: \_\_\_\_\_

385. Report Status: \_\_\_\_\_

386. Report Date: \_\_\_\_\_

387. Report Time: \_\_\_\_\_

388. Report Location: \_\_\_\_\_

389. Report Category: \_\_\_\_\_

390. Report Subcategory: \_\_\_\_\_

391. Report Severity: \_\_\_\_\_

392. Report Outcome: \_\_\_\_\_

393. Report Status: \_\_\_\_\_

394. Report Date: \_\_\_\_\_

395. Report Time: \_\_\_\_\_

396. Report Location: \_\_\_\_\_

397. Report Category: \_\_\_\_\_

398. Report Subcategory: \_\_\_\_\_

399. Report Severity: \_\_\_\_\_

400. Report Outcome: \_\_\_\_\_

401. Report Status: \_\_\_\_\_

402. Report Date: \_\_\_\_\_

403. Report Time: \_\_\_\_\_

404. Report Location: \_\_\_\_\_

405. Report Category: \_\_\_\_\_

406. Report Subcategory: \_\_\_\_\_

407. Report Severity: \_\_\_\_\_

408. Report Outcome: \_\_\_\_\_

409. Report Status: \_\_\_\_\_

410. Report Date: \_\_\_\_\_

411. Report Time: \_\_\_\_\_

412. Report Location: \_\_\_\_\_

413. Report Category: \_\_\_\_\_

414. Report Subcategory: \_\_\_\_\_

415. Report Severity: \_\_\_\_\_

416. Report Outcome: \_\_\_\_\_

417. Report Status: \_\_\_\_\_

418. Report Date: \_\_\_\_\_

419. Report Time: \_\_\_\_\_

420. Report Location: \_\_\_\_\_

421. Report Category: \_\_\_\_\_

422. Report Subcategory: \_\_\_\_\_

423. Report Severity: \_\_\_\_\_

424. Report Outcome: \_\_\_\_\_

425. Report Status: \_\_\_\_\_

426. Report Date: \_\_\_\_\_

427. Report Time: \_\_\_\_\_

428. Report Location: \_\_\_\_\_

429. Report Category: \_\_\_\_\_

430. Report Subcategory: \_\_\_\_\_

431. Report Severity: \_\_\_\_\_

432. Report Outcome: \_\_\_\_\_

433. Report Status: \_\_\_\_\_

434. Report Date: \_\_\_\_\_

435. Report Time: \_\_\_\_\_

436. Report Location: \_\_\_\_\_

437. Report Category: \_\_\_\_\_

438. Report Subcategory: \_\_\_\_\_

439. Report Severity: \_\_\_\_\_

440. Report Outcome: \_\_\_\_\_

441. Report Status: \_\_\_\_\_

442. Report Date: \_\_\_\_\_

443. Report Time: \_\_\_\_\_

444. Report Location: \_\_\_\_\_

445. Report Category: \_\_\_\_\_

446. Report Subcategory: \_\_\_\_\_

447. Report Severity: \_\_\_\_\_

448. Report Outcome: \_\_\_\_\_

449. Report Status: \_\_\_\_\_

450. Report Date: \_\_\_\_\_

451. Report Time: \_\_\_\_\_

452. Report Location: \_\_\_\_\_

453. Report Category: \_\_\_\_\_

454. Report Subcategory: \_\_\_\_\_

455. Report Severity: \_\_\_\_\_

456. Report Outcome: \_\_\_\_\_

457. Report Status: \_\_\_\_\_

458. Report Date: \_\_\_\_\_

459. Report Time: \_\_\_\_\_

460. Report Location: \_\_\_\_\_

461. Report Category: \_\_\_\_\_

462. Report Subcategory: \_\_\_\_\_

463. Report Severity: \_\_\_\_\_

464. Report Outcome: \_\_\_\_\_

465. Report Status: \_\_\_\_\_

466. Report Date: \_\_\_\_\_

467. Report Time: \_\_\_\_\_

468. Report Location: \_\_\_\_\_

469. Report Category: \_\_\_\_\_

470. Report Subcategory: \_\_\_\_\_

471. Report Severity: \_\_\_\_\_

472. Report Outcome: \_\_\_\_\_

473. Report Status: \_\_\_\_\_

474. Report Date: \_\_\_\_\_

475. Report Time: \_\_\_\_\_

476. Report Location: \_\_\_\_\_

477. Report Category: \_\_\_\_\_

478. Report Subcategory: \_\_\_\_\_

479. Report Severity: \_\_\_\_\_

480. Report Outcome: \_\_\_\_\_

481. Report Status: \_\_\_\_\_

482. Report Date: \_\_\_\_\_

483. Report Time: \_\_\_\_\_

484. Report Location: \_\_\_\_\_

485. Report Category: \_\_\_\_\_

486. Report Subcategory: \_\_\_\_\_

487. Report Severity: \_\_\_\_\_

488. Report Outcome: \_\_\_\_\_

489. Report Status: \_\_\_\_\_

490. Report Date: \_\_\_\_\_

491. Report Time: \_\_\_\_\_

492. Report Location: \_\_\_\_\_

493. Report Category: \_\_\_\_\_

494. Report Subcategory: \_\_\_\_\_

495. Report Severity: \_\_\_\_\_

496. Report Outcome: \_\_\_\_\_

497. Report Status: \_\_\_\_\_

498. Report Date: \_\_\_\_\_

499. Report Time: \_\_\_\_\_

500. Report Location: \_\_\_\_\_

# Reporting Foreign Events

- U.S. based companies marketing devices OUS must report:
  - If a similar version is sold in the U.S.
  - If it is a 510(k) exempt device listed in the U.S. for a U.S. registered manufacturer.
- Foreign Manufacturers marketing a device solely OUS:
  - Not required to report if not FDA-cleared/approved and no similar version sold in U.S.

# Not Reportable

- Manufacturers are not required to submit an MDR report if:
  - They determine that the information received is erroneous in that a device-related adverse event did not occur. Retain documentation.
  - They did not manufacture or import the device about which you have adverse event information
  - They are a contract manufacturer who does not distribute or market the devices it manufactures for a specification developer
  - They are a foreign manufacturer:
    - Who markets solely OUS, and
    - Has not received premarket clearance/ approval for OUS device, and
    - There is no similar version of the OUS device in the US

# Additional Requirements

- Develop, maintain, and implement written MDR procedures
- Establish and maintain MDR event files
- Have a system in place that ensures access to information that facilitates timely follow up/inspection by FDA



# MDR Adverse Event Codes

- A system of codes, terms, and definitions used to describe and categorize medical device adverse events.
- Primarily used to complete MDRs

# MDR Code Types

Code Type	Purpose: These Terms/Codes Describe
Medical Device Problem	Problems (malfunction, deterioration of function, failure) of medical devices
Medical Device Component	The parts and components which were involved in, or affected by, the medical device adverse event/incident.
Cause Investigation - Type of Investigation	What was investigated and what kind of investigation was conducted to specify the root cause of the adverse event.
Cause Investigation - Investigation Findings	The findings in the specific investigation that are the keys to identify the root cause of the event.
Cause Investigation - Investigation Conclusion	The conclusion regarding the root cause of the reported event.
Health Effects - Clinical Signs and Symptoms or Conditions	The clinical signs and symptoms or conditions of the affected person appearing as a result of the medical device adverse event/incident.
Health Effects - Health Impact	The consequences of the medical device adverse event/incident on the person affected.

# MDR Codes and IMDRF

- FDA is a participant in the IMDRF Adverse Event Terminology working group
- Aim of the WG is to improve and harmonize medical device adverse event coding among participating regulatory authorities
- [Terminologies for Categorized Adverse Event Reporting \(AER\): terms, terminology and codes](#) was published 20 April 2020
- FDA codes are mapped to a single corresponding IMDRF code



# Manufacturer and User Facility Device Experience (MAUDE)

- MAUDE is a searchable database containing 10 years worth of data on medical device adverse events
- Passive surveillance system that is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices
- FDA reviews all MDRs received

# MAUDE

- <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm>

**Search Database**

 Help
  Download Files



Product Problem

Product Class

Event Type  Manufacturer

Model Number  Report Number

Brand Name  Product Code

Date Report Received by FDA (mm/dd/yyyy)   to  

[Go to Simple Search](#)
 Records per Report Page
 [Clear Form](#)

# Medical Device Recalls

- A recall is a method of removing or correcting products that are in violation of laws administered by the Food and Drug Administration (FDA).
- A recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective.
- [21 CFR 7](#) provides guidance so that responsible firms may conduct an effective recall.
- FDA does have the authority to issue a recall order to the manufacturer per [21 CFR 810](#), but this is very rare.

## Classification of Recalls

- A health hazard evaluation (HHE) must be conducted to determine the cause of an adverse event involving a medical device
- FDA will assign the recall a classification (Class I, II, or III) to indicate the relative degree of health hazard of the product being recalled or considered for recall

# Classification of Recalls

- Class I - a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
- Class II - a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III - a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.



# Recall Strategy

- The recalling firm should develop a recall strategy that takes into account the following factors as they apply to the individual circumstances of the particular recall:
  - Results of health hazard evaluation.
  - Ease in identifying the product.
  - Degree to which the product's deficiency is obvious to the consumer or user.
  - Degree to which the product remains unused in the market-place.
  - Continued availability of essential products.
- The FDA will review the adequacy of a proposed recall strategy and recommend changes as appropriate. A recalling firm should conduct the recall in accordance with an approved recall strategy but need not delay initiation of a recall pending review of its recall strategy.

# Recall Strategy

- A recall strategy will address the following elements:
  - Depth of the recall – strategy will specify the level in the distribution chain to which the recall is to extend
  - Public warning – recalling firm is requested to submit proposed public warning. If FDA feels this is inadequate and firm doesn't revise, FDA can issue its own press
  - Effectiveness checks – recalling firm is responsible for determining how effective the recall has been and if consignees have received notification about the recall and have taken appropriate action. FDA will assist in this task where necessary and appropriate.

# Corrections and Removals

- Under [21 CFR 806](#), Medical Devices; Reports of Corrections and Removals, manufacturers and importers are required to make a report to FDA of any correction or removal of a medical device(s) if the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health.
- A report must be made even if the event was caused by user error.

# Corrections and Removals

- The definition of "risk to health" under 21 CFR 806 tracks the definitions of Class I and Class II recalls in 21 CFR 7.3(m). Therefore, reports of corrections and removals are required for Class I and Class II recalls.
- Under 21 CFR 806, manufacturers and importers need not report events categorized as Class III recalls under 21 CFR §7; only record keeping requirements would apply.
- The following actions are exempt from the reporting requirements:
  - Actions taken by device manufacturers or importers to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the act caused by the device,
    - Market withdrawals,
    - Routine servicing, and
    - Stock recoveries.

## Corrections and Removals – When to Report?

- The report must be submitted to FDA within 10 working days from the time the firm initiates the correction or removal . If there is not a "risk to health" involved, a report to FDA is not required, but the manufacturer or importer must keep a record of the correction or removal.

# Corrections and Removals – Recordkeeping Requirements

- The device manufacturer or importer who initiates a correction or removal of a device that is not required to be reported to FDA must maintain records of the correction or removal.
- Records must be retained for a period of two years beyond the expected life of the device, even if the manufacturer or importer has ceased to manufacture or import the device. Records required to be maintained must be transferred to the new manufacturer or importer of the device and maintained for the required period of time.

# Recalls Database

- <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm>



## Medical Device Recalls

[FDA Home](#)
[Medical Devices](#)
[Databases](#)

This database contains Medical Device Recalls classified since November 2002. Since January 2017, it may also include correction or removal actions initiated by a firm prior to review by the FDA. The status is updated if the FDA identifies a violation and classifies the action as a recall and again when the recall is terminated. FDA recall classification may occur after the firm recalling the medical device product conducts and communicates with its customers about the recall. Therefore, the recall information posting date ("create date") indicates the date FDA classified the recall, it does not necessarily mean that the recall is new. [CBER recall information is available here.](#) [More about Medical Device Recalls](#)

### Search Database



Product Name	<input type="text"/>	Product Code	<input type="text"/>	In Vitro Devices	<input type="checkbox"/>
Recall Class	<input type="text" value="All"/>	PMA/510(K) Number	<input type="text"/>		
Recall Date	<input type="text"/>		to	<input type="text"/>	
	<input type="text"/>			Recall Number	
Reason for Recall	<input type="text"/>				
Recalling Firm	<input type="text"/>				
Root Cause	<input type="text"/>				
Sort by	<input type="text" value="Date Record Classified (Descending)"/>				

[Quick Search](#)

[Clear Form](#)

# Resources

Resource	URL
Medical Device Tracking 21 CFR Part 21	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=821">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=821</a>
Medical Device Tracking – Guidance for Industry and FDA Staff	<a href="https://www.fda.gov/media/71205/download">https://www.fda.gov/media/71205/download</a>
Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act	<a href="https://www.fda.gov/media/81015/download">https://www.fda.gov/media/81015/download</a>
Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order	<a href="https://www.fda.gov/media/71327/download">https://www.fda.gov/media/71327/download</a>
Medical Device Reporting 21 CFR Part 803	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=803">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=803</a>
Medical Device Reporting for Manufacturers	<a href="https://www.fda.gov/media/86420/download">https://www.fda.gov/media/86420/download</a>
Medical Device Reporting for User Facilities	<a href="https://www.fda.gov/media/73972/download">https://www.fda.gov/media/73972/download</a>
Questions and Answers about eMDR	<a href="https://www.fda.gov/media/76993/download">https://www.fda.gov/media/76993/download</a>
Enforcement Policy 21 CFR Part 7	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=7">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=7</a>
Medical Device Recall Authority 21 CFR Part 810	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=810">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=810</a>
Medical Devices; Reports of Corrections and Removals 21 CFR Part 806	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=806">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=806</a>



