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Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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Preface

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Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

FDA developed this document to provide guidance to industry and FDA staff about best practices in selecting a predicate device for premarket notification [510(k)] submissions. Specifically, this guidance recommends four (4) best practices to employ when selecting a predicate device used to support a 510(k) submission. The recommendations provided in this guidance are not intended to propose any changes to applicable statutory and regulatory standards, such as how FDA evaluates substantial equivalence, or the applicable requirements, including the requirement for valid scientific evidence. FDA developed this guidance to improve the predictability, consistency, and transparency of the 510(k) premarket review process. This guidance and associated recommendations are consistent with and are intended to be used in conjunction with the FDA guidance “[The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notifications \[510\(k\)\]](#)”¹ (hereinafter, 510(k) Program Guidance) and other relevant FDA guidances on 510(k) submissions.

In general, FDA’s guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

¹ Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k>.

35 **II. Background**

36 **A. The 510(k) Process**

37 The framework under which FDA regulates medical devices was put into place when Congress
38 enacted the Medical Device Amendments (Pub. L. 94-295) to the Federal Food, Drug, and
39 Cosmetic Act (FD&C Act) on May 28, 1976. Under section 510(k) of the FD&C Act, a
40 manufacturer must submit a premarket notification (often referred to as a 510(k)) to FDA at least
41 90 days before introducing, or delivering for introduction, a device into interstate commerce for
42 commercial distribution so the Agency can determine whether or not the device meets the criteria
43 for market clearance (sections 510(k), 510(n), and 513(i) of the FD&C Act). A 510(k) is required
44 for devices intended for human use, for which a premarket approval application (PMA) is not
45 required, unless the device is exempt from the 510(k) requirements of the FD&C Act and does
46 not exceed the relevant limitations of exemptions in the device classification regulations.

47
48 A 510(k) is a marketing submission made by a manufacturer to FDA to demonstrate that the
49 device to be marketed is substantially equivalent to a “predicate device” (section 513(i) of the
50 FD&C Act and 21 CFR 807.92(a)(3)-(6)). Substantial equivalence is rooted in a comparison
51 between the “new device”² and predicate device(s).³

52
53 The Agency bases its decision on whether the device is substantially equivalent (SE) to a
54 predicate device using the statutory criteria in section 513(i) of the FD&C Act. For FDA to find a
55 new device SE to a predicate device, FDA must first find that the new device and predicate
56 device have the same intended use. FDA must then find that the new device and predicate device
57 have the same technological characteristics, or if they do not, that the different technological
58 characteristics⁴ of the new device do not raise different questions of safety and effectiveness and
59 that the new device is as safe and effective as a predicate device. FDA conducts this evaluation
60 by reviewing the proposed scientific methods for evaluating new/different technological
61 characteristics’ effects on safety and effectiveness and accompanying performance data to
62 determine whether the methods are acceptable and whether the data demonstrates SE. A new
63 device requiring premarket notification cannot be introduced into interstate commerce for

² For purposes of this guidance, a “new device” means a device within the meaning of section 201(h) of the FD&C Act that is not legally marketed. It can be either a completely new device (i.e., one that has not received FDA’s marketing authorization) or a modification of a legally marketed device that would require a new 510(k).

³ A predicate device is a legally marketed device. Under 21 CFR 807.92(a)(3), a legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I, or a device which has been found to be substantially equivalent through the 510(k) premarket notification process. Moreover, “[a] device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of [FDA] or that has been determined to be misbranded or adulterated by a judicial officer.” Section 513(i)(2) of the FD&C Act.

⁴ For purposes of an SE determination, “different technological characteristics” means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.” Section 513(i)(1)(B) of the FD&C Act.

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64 commercial distribution until FDA issues an order stating that the device has been determined to
65 be SE (section 513(f)(1) of the FD&C Act).⁵
66

67 **B. 510(k) Modernization**

68 In April 2018, CDRH issued the [Medical Device Safety Action Plan: Protecting Patients,](#)
69 [Promoting Public Health](#)⁶ (herein referred to as the “Safety Action Plan”) to communicate
70 CDRH’s vision for modernizing measures to improve the safety of medical devices while
71 continuing to create more efficient pathways to bring critical devices to patients. The [Safety](#)
72 [Action Plan](#) describes the efforts underway to modernize the 510(k) program.
73

74 In November 2018, FDA announced transformative new steps to modernize FDA’s 510(k)
75 program to advance the review of the safety and effectiveness of medical devices. In connection
76 with this announcement, FDA also requested public feedback on these steps to continue to
77 modernize the framework for 510(k) review while promoting innovation and improving safety
78 by driving innovators toward reliance on more modern predicate devices or objective
79 performance criteria when they seek to bring new devices to the market and ultimately to
80 patients. FDA indicated that it is looking at ways to promote the use of more recent predicates
81 because it believes that newer devices should be compared to the benefits and risks of more
82 modern technology.
83

84 To advance these goals, FDA discussed several potential options for 510(k) modernization. The
85 statement discussed that the Agency considered making public on its website those cleared
86 devices that demonstrated substantial equivalence to older predicate devices. FDA also
87 considered focusing on predicates that were more than ten (10) years old as a starting point, so
88 the public was made aware of those technologies. FDA’s goal in focusing on older predicates
89 was to encourage manufacturers to continually offer patients devices with the latest
90 improvements and advances. FDA issued a public notice on January 22, 2019⁷ on FDA’s website
91 that requested public comment on this proposal.
92

93 FDA reviewed all comments submitted to the docket and acknowledges that the initial proposal
94 of focusing only on older predicates may not optimally promote safer and more effective
95 devices. For example, if selecting a predicate for an implant, older devices may potentially have
96 long-term safety and effectiveness data that establishes a history of safe and effective use.
97 Conversely, when selecting a predicate for a device that includes software, a more recently

⁵ Under section 510(k) of the FD&C Act, premarket notification is required for devices that are not subject to a premarket approval application, unless the device is exempt from the 510(k) requirements of the FD&C Act and does not exceed the limitations of exemptions for each of the device classification regulations (e.g., 21 CFR Parts 862-892).

⁶ Available at <https://www.fda.gov/about-fda/cdrh-reports/medical-device-safety-action-plan-protecting-patients-promoting-public-health>.

⁷ Available at <https://wayback.archive-it.org/7993/20190206202131/https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm604500.htm>. Public comments submitted can be searched under the docket FDA-2018-N-4751, available at <https://www.regulations.gov/docket/FDA-2018-N-4751/comments>.

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98 cleared device could include modern safety features due to rapid technological advances that
99 affect cybersecurity, interoperability, and modern software architectures.

100

101 After considering the docket comments, FDA believes that it may be more appropriate to
102 modernize the 510(k) process with respect to the use of predicate devices by focusing on
103 utilizing best practices when selecting a predicate device rather than just their age. Therefore,
104 FDA is issuing this draft guidance to propose ways to encourage the use of best practices when
105 selecting a predicate device.

106

107 FDA developed this draft guidance to propose factors for consideration as best practices for
108 choosing a predicate device. These best practices include consideration of the characteristics of
109 predicate devices rather than focusing on the age of the predicate. FDA believes that this will
110 encourage the evolution of safer and more effective medical devices in the 510(k) program over
111 time. Additionally, FDA believes that identification of the characteristics of predicate devices
112 used to support a 510(k) submission in the accompanying 510(k) Summary may provide
113 additional transparency to the public for devices subject to 510(k) requirements.⁸

114

III. Scope

116 This guidance provides recommendations to industry and FDA staff about the best practices of
117 choosing a predicate device for a 510(k) submission. This guidance is intended to be used in
118 conjunction with the [510\(k\) Program Guidance](#).⁹ The recommendations provided in this
119 guidance are not intended to propose any changes to applicable statutory and regulatory
120 standards, such as how FDA evaluates substantial equivalence, or the applicable requirements,
121 including the requirement for valid scientific evidence. FDA developed this guidance to improve
122 the predictability, consistency, and transparency of the 510(k) premarket review process.

123

124 This guidance is also not intended to supplant existing device-specific guidance but may cover
125 broader areas not addressed in device-specific guidances.

126

IV. How to use this guidance

128 This guidance is intended to guide submitters through the best practices in selecting a predicate
129 device for a 510(k) submission. This guidance is intended to be used while a submitter is
130 preparing their 510(k) submission to assist with the identification of potential predicate device(s)
131 to support their device's substantial equivalence to a legally marketed device. Based on FDA's
132 experience in reviewing 510(k) submissions, the Agency is aware that many submitters include

⁸ Consistent with the [510\(k\) Program Guidance](#) and as specified in 21 CFR 807.92(a)(6), the 510(k) Summary shall contain the following information: "If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device identified in [21 CFR 807.92(a)(3)], a summary of the technological characteristics of the subject device in comparison to those of the predicate device. If the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in [21 CFR 807.92(a)(3)]."

⁹ Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k>.

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133 in their 510(k) submission a completed 510(k) flowchart with a discussion describing why the
134 submitter believes their device is substantially equivalent to the predicate device.¹⁰

135

136 When considering the selection of predicate devices during 510(k) submission preparation,
137 submitters should consider the list of legally marketed devices that they believe have the same
138 intended use as the subject device and when any differences in technological characteristics do
139 not raise different questions about safety and effectiveness, hereafter referred to as a “valid
140 predicate device.”^{11, 12} FDA recommends narrowing this list of valid predicate device(s) to the
141 predicate device¹³ identified by the submitter to support the 510(k) submission using the best
142 practices outlined in Section V of this guidance, in conjunction with the [510\(k\) Program
143 Guidance](#).¹⁴ A visual representation of this concept is illustrated in Figure 1 below.

144

145

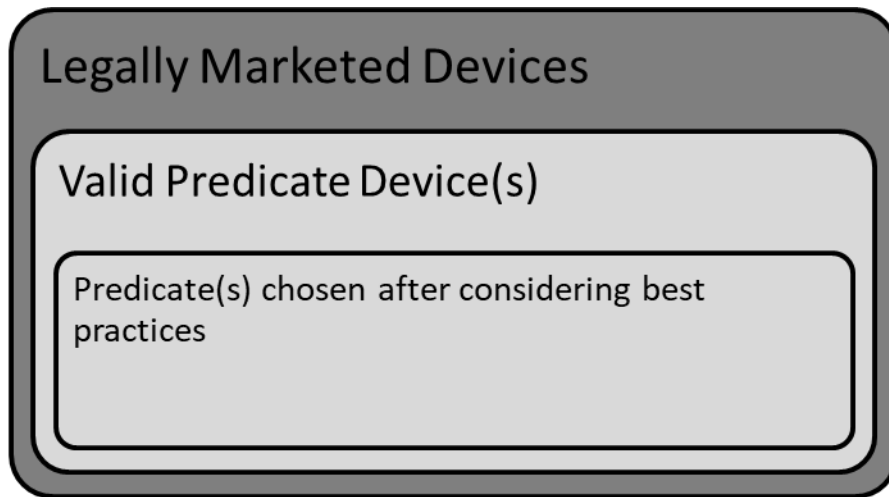
¹⁰ For example, FDA has guidance on the “[Format for Traditional and Abbreviated 510\(k\)s](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/format-traditional-and-abbreviated-510ks),” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/format-traditional-and-abbreviated-510ks>. Submitters could include such an assessment in Section 12 (Substantial Equivalence Discussion) of their 510(k) submission.

¹¹ Consistent with sections 510(k), 510(n), and 513(i) of the FD&C Act and the [510\(k\) Program Guidance](#), while submitters propose a predicate device in their 510(k) submission, FDA determines whether a subject and predicate device are substantially equivalent. This determination includes whether a valid predicate device exists for the subject device.

¹² Consistent with the [510\(k\) Program Guidance](#), if FDA has established special controls applicable to the device type, the 510(k) would also need to demonstrate that the proposed device meets the relevant special controls for the device to be classified into class II.

¹³ Consistent with the [510\(k\) Program Guidance](#), a submitter may use multiple predicate devices to help demonstrate substantial equivalence in certain circumstances. Submitters sometimes choose to do this when combining features from two or more predicate devices with the same intended use into a single new device, when seeking to market a device with more than one intended use, or when seeking more than one indication for use under the same intended use. Additionally, while FDA does not consider reference devices to be predicate devices, reference devices can be used to support a 510(k) submission beyond Decision 4 in the 510(k) flowchart (See Appendix A in the [510\(k\) Program Guidance](#)). For example, reference devices can be used to support scientific methodology or standard reference values at Decision 5a in the 510(k) flowchart.

¹⁴ Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k>.



146
147 **Figure 1.** Visual depiction of the relevant terminology used in this guidance.

148
149 FDA recommends the submitter include within their 510(k) submission how they used the best
150 practices identified in this guidance in selecting the predicate device(s) used to support the
151 510(k) submission. For example, if a valid predicate device consistent with the best practices
152 identified in this guidance is not available, FDA recommends describing in the 510(k)
153 submission how any known concerns with the valid predicate device have been mitigated with
154 the subject device (e.g., design features, performance testing). FDA also recommends that the
155 submitter summarize how the best practices were utilized in the selection of the predicate device
156 used to support the 510(k) submission in the 510(k) Summary (See Section VI of this guidance).
157 These recommendations are intended to aid the submitter in selecting a predicate for their device
158 and help provide additional transparency to the public in the 510(k) summary if the 510(k)
159 submission is cleared by FDA.
160

161 **V. Best practices for selecting a predicate device**

162 FDA identifies all devices cleared through the 510(k) process in the publicly available [FDA](#)
163 [510\(k\) Premarket Notification Database](#).¹⁵ This online database is updated monthly by FDA.
164 Most submitters likely start with basic administrative information to identify valid predicate
165 device(s), including but not limited to the:

- 166 • Trade names of similar devices;
- 167 • Manufacturer(s) of similar devices;
- 168 • 510(k) numbers for similar devices; and
- 169 • Searching of classification information (e.g., product codes, classification regulation) for
170 similar devices.

171
¹⁵ Available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>.

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172 Once legally marketed devices have been identified, FDA recommends reviewing the publicly-
173 available 510(k) Summary¹⁶ and Indications for Use documents for each device being considered
174 by the submitter as a valid predicate device. In addition to these basic administrative items, FDA
175 recommends submitters apply the best practices identified below when selecting a predicate
176 device to support the 510(k) submission.
177

178 **A. Predicate devices cleared using well-established methods**

179 FDA recommends selecting a valid predicate device that was cleared using well-established
180 methods.¹⁷ These methods include those from a currently FDA-recognized voluntary consensus
181 standard,¹⁸ an FDA guidance document,¹⁹ a qualified medical device development tool
182 (MDDT),²⁰ or a widely available and accepted method published in the public domain or
183 scientific literature for the context of use, or found acceptable through the submitter's own
184 previous premarket submission. FDA recommends prioritizing predicate devices with methods
185 developed within a consensus environment, and those subject to public comment or peer review.
186 FDA believes that when selecting a valid predicate device, submitters should consider how much
187 information is available regarding the test method(s) used in support of the predicate device's
188 510(k) clearance and whether those methods continue to be appropriate for evaluating the subject
189 device. For example, voluntary consensus standards periodically undergo revisions and the
190 methods used to evaluate devices can change with both industry and FDA experience with a
191 device.

192
193 Once the submitter has identified a list of valid predicate devices, FDA recommends conducting
194 a search of the nonclinical tests submitted, referenced, or relied on in the 510(k) submission²¹ to
195 support a determination of substantial equivalence. For example, when selecting between two
196 similar valid predicate devices, where one identified performing testing using FDA guidance and

¹⁶ As specified in 21 CFR 807.87(h), a 510(k) Statement as described in 21 CFR 807.93 may be provided by the submitter in lieu of a 510(k) Summary. However, in order to facilitate transparency, FDA encourages all submitters to utilize the 510(k) Summary option.

¹⁷ FDA acknowledges this information may not always be publicly available for a predicate device, especially for those that were not recently cleared.

¹⁸ For the current edition of FDA-recognized standard(s), see the [Recognized Consensus Standards Database](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm), available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>. For more information regarding use of consensus standards in regulatory submissions, refer to the FDA guidance titled "[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices)," available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>.

¹⁹ A list of FDA guidance documents is available on FDA's website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

²⁰ A list of qualified MDDTs is available on FDA's website at <https://www.fda.gov/medical-devices/medical-device-development-tools-mddt>.

²¹ In accordance with 21 CFR 807.92(a)(3), the 510(k) Summary must identify the predicate relied upon for a substantial equivalence determination. In accordance with 21 CFR 807.92, FDA describes the requirements and recommendations of the content to be included in a 510(k) Summary in Appendices B and C of the [510\(k\) Program Guidance](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmm/pmn.cfm). 510(k) Summaries for devices that have been cleared for marketing through the FDA can be found in the [510\(k\) Premarket Notification Database](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmm/pmn.cfm) on the FDA website at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmm/pmn.cfm>.

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197 FDA recognized voluntary consensus standards while the other did not, FDA recommends the
198 submitter select the valid predicate device in which testing relied on these well-established
199 methods. FDA considers it a best practice to select a predicate that was cleared using well-
200 established methods, as this will continue to advance the 510(k) Program, by encouraging the
201 evolution of safer and more effective medical devices in the 510(k) program over time, and
202 ensure that the subject device is evaluated using updated scientific methods whenever possible.
203

204 **B. Predicate devices meet or exceed expected safety and**
205 **performance**

206 FDA considers it a best practice to select a valid predicate device that continues to perform
207 safely and as intended by the manufacturer during use in its intended environment of use
208 whenever possible. FDA recommends selecting a valid predicate device after considering how
209 any reported medical device-related adverse events, malfunctions, or deaths may have a role in
210 the safety and effectiveness of the device. New information about a device’s safety and/or
211 effectiveness, including unanticipated adverse events, may become available once the device is
212 more widely distributed and used commercially. Also, subsequent changes made to the device,
213 including material changes, or its manufacturing process may lead to unanticipated effects that
214 cannot be comprehensively captured during premarket review.²² This new information may
215 include, but is not limited to, a newly recognized type of adverse event associated with a medical
216 device, an increase in the severity or frequency of a known adverse event, new product-product
217 interactions, or device malfunctions.

218
219 Once the submitter has identified a list of valid predicate devices, FDA recommends conducting
220 a search for any reported injury, deaths, or malfunctions using the following FDA databases:

- 221 • [Manufacturer and User Facility Device Experience \(MAUDE\) Database](#),²³
 - 222 • [Medical Device Reporting \(MDR\) Database](#),²⁴ and
 - 223 • [MedSun Reports Database](#).²⁵
- 224

225 FDA recommends searching each of the above databases for any reports of unexpected injury,
226 deaths, or malfunctions associated with the available valid predicate devices. For example, when
227 selecting a predicate device for an infusion pump, if the database search reveals a high frequency
228 of reports of battery failures related to the predicate device that resulted in serious injuries to the
229 operator, such events could suggest fundamental design issues with this valid predicate device
230 and FDA recommends selection of a different valid predicate device for the 510(k) submission

²² The regulatory criteria for when a premarket notification submission is required for a change to an existing device are outlined in 21 CFR 807.81(a)(3). For more information regarding when a premarket modification submission is required refer to the FDA guidance titled, “[Deciding When to Submit a 510\(k\) for a Change to an Existing Device](#),” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device>, and the FDA guidance titled, “[Deciding When to Submit a 510\(k\) for a Software Change to an Existing Device](#),” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-software-change-existing-device>.

²³ Available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>.

²⁴ Available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmdr/search.cfm>.

²⁵ Available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/searchreporttext.cfm>.

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231 whenever possible. If another valid predicate device is not available, FDA recommends that the
232 submitter describe in the 510(k) submission how the subject device mitigates the known
233 concerns with the predicate device used to support the 510(k) submission.
234

235 **C. Predicate devices without unmitigated use-related or design-**
236 **related safety issues**

237 FDA recommends selecting a valid predicate device that does not have unmitigated use-related
238 or design-related safety issues, including consideration of emerging signals or safety
239 communications.²⁶ New information about a device’s safety and/or effectiveness can become
240 available once the device is more widely distributed and used. This new information could
241 represent a signal and may include information related to device malfunctions or patient injuries
242 potentially related to improper device use or design.
243

244 Consistent with the FDA guidance “[Public Notification of Emerging Postmarket Medical Device](#)
245 [Signals \(“Emerging Signals”\)](#),”²⁷ an emerging signal is new information about a device that
246 supports a new causal association or a new aspect of a known association between a device and
247 an adverse event or set of adverse events and for which FDA has conducted an initial evaluation
248 and determined that the information has the potential to impact patient management decisions
249 and/or the known benefit-risk profile of the device. An emerging signal may be associated with
250 one product from one manufacturer, one type of product or similar products from multiple
251 manufacturers, or multiple different product types from multiple different manufacturers (e.g.,
252 materials issues). Information about emerging signals and safety communications is available on
253 the [Medical Device Safety](#)²⁸ and [CBER Safety & Availability \(Biologics\)](#)²⁹ websites. FDA
254 recommends reviewing any safety signals, emerging signals, or other safety information
255 available prior to selecting a valid predicate device to support the 510(k) submission.
256

257 Once the submitter has identified a list of valid predicate devices, FDA recommends conducting
258 a search of the [Medical Device Safety](#) and [CBER Safety & Availability \(Biologics\)](#) websites to
259 assess whether any of the valid predicate devices have an associated use-related or design-related
260 safety issue. For example, a signal was reported for duodenoscopes describing challenges in the
261 adequacy of reprocessing instructions that resulted in a potential for disease transmission.³⁰ This
262 signal resulted in an effort to replace traditionally reprocessed duodenoscopes with
263 duodenoscopes which had innovative designs to enhance safety, including designs with
264 disposable caps or distal ends. FDA considers it a best practice to select a valid predicate device
265 that is not associated with emerging signals or safety communications that relate to unmitigated
266 use-related or design-related safety issues whenever possible.
267

²⁶ Available at <https://www.fda.gov/medical-devices/medical-device-safety>.

²⁷ Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/public-notification-emerging-postmarket-medical-device-signals-emerging-signals>.

²⁸ Available at <https://www.fda.gov/medical-devices/medical-device-safety>.

²⁹ Available at <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics>.

³⁰ Available at <https://www.fda.gov/medical-devices/safety-communications/use-duodenoscopes-innovative-designs-enhance-safety-fda-safety-communication>.

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268 **D. Predicate devices without an associated design-related recall**

269 FDA recommends selecting a valid predicate device that has not been subject to a design-related
270 recall.³¹ Recalls are typically voluntary actions taken by a manufacturer or may be requested by
271 FDA to correct or remove a violative product from the market.³² A violative product is one in
272 violation of the laws that FDA administers and against which FDA would initiate legal action.
273 Recalls can occur due to design defects, manufacturing defects, or labeling defects.

274
275 Design-related recalls can indicate a fundamental flaw with the design of the device as cleared
276 and commercially distributed. Design controls under 21 CFR 820.30 include a framework that
277 requires manufacturers subject to these requirements to establish and maintain procedures to
278 control the design of the device in order to ensure that specified design requirements are met.^{33,34}
279 When a design-related recall has been conducted for a device, adequate design control
280 procedures, including but not limited to design input, output, verification, validation, and transfer
281 may not have been adequately implemented through the design process. In some instances, the
282 underlying root cause of the design related issues identified as part of a design-related recall may
283 not be available or a correction of these design-related issues may not be possible. Further,
284 although the methods and performance data provided in the 510(k) submission for the valid
285 predicate device subject to a subsequent design-related recall were sufficient to support a
286 substantial equivalence determination at that time of 510(k) clearance, utilization of such a valid
287 predicate device may not be ideal to use for future 510(k) submissions.

288
289 Once the submitter has identified a list of valid predicate devices, FDA recommends conducting
290 a search of the [Medical Device Recalls Database](#) to assess whether any of the valid predicate
291 devices have an associated recall. For example, the recall of a coronary catheter tip for fracture
292 could be associated with a change in the manufacturing process or with the materials used in the
293 design of the catheter. If a recall is associated with the materials used in the catheter, this could
294 be considered a design-related recall when it is due to an inadequacy of that material to meet user

³¹ The [Medical Device Recalls Database](#) is available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm>, and includes recalls classified since November 2002.

³² While FDA focuses on voluntary recalls conducted under 21 CFR Part 7, FDA may, after providing the appropriate person with an opportunity to consult with the Agency, also require that a manufacturer recall their device when the criteria are met under 21 CFR Part 810.

³³ For devices subject to 510(k) requirements, design controls apply to class II devices and those class I devices listed in 21 CFR 820.30(a)(2).

³⁴ On February 23, 2022, FDA proposed to amend the device Quality System Regulation, 21 CFR Part 820, to align more closely with international consensus standards for devices ([87 FR 10119](#); available at <https://www.federalregister.gov/documents/2022/02/23/2022-03227/medical-devices-quality-system-regulation-amendments>). Specifically, FDA proposed to withdraw the majority of the current requirements in Part 820 and instead incorporate by reference the 2016 edition of the International Organization for Standardization (ISO) 13485, Medical devices – Quality management systems for regulatory purposes, in Part 820. As stated in that proposed rule, the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the current Part 820, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the FD&C Act. FDA intends to finalize this proposed rule expeditiously. When the final rule takes effect, FDA will also update the references to provisions in 21 CFR Part 820 in this guidance to be consistent with that rule.

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295 needs and intended uses. The material used in the design of this catheter and the testing
296 conducted on the predicate device did not adequately mitigate against the risk of tip fracture,
297 resulting in a design-related recall. FDA considers it a best practice to select a valid predicate
298 device that is not associated with a design-related recall whenever possible.
299

300 **VI. Improving the Transparency of Predicate Devices**

301 The 510(k) Summary is a document that provides an adequate summary of any information
302 respecting safety and effectiveness and must include all the elements identified in 21 CFR
303 807.92.³⁵ A 510(k) Summary must be in sufficient detail to provide an understanding of the basis
304 for a determination of substantial equivalence (21 CFR 807.92(a)). In Appendix B of the [510\(k\)](#)
305 [Program Guidance](#), FDA describes the requirements of the content to be included in a 510(k)
306 Summary, in accordance with 21 CFR 807.92, and provides recommendations on the
307 information to be included in a 510(k) Summary to ensure compliance with 21 CFR 807.92 and
308 consistency in the level of information conveyed and captured in the 510(k) Summaries that are
309 available to the public on FDA’s website.
310

311 In an effort to improve the transparency and predictability of the 510(k) program and to ensure
312 that the 510(k) Summary reflects the information provided in a 510(k) submission to support a
313 substantial equivalence determination, FDA stated in the [510\(k\) Program Guidance](#) that the
314 Agency intends to verify the accuracy and completeness of the information included in a 510(k)
315 Summary.
316

317 Although the 510(k) Summary is a document drafted by the submitter and is included in the
318 510(k), revisions to the 510(k) Summary may be necessary to accurately reflect FDA’s decision-
319 making process. As stated in the [510\(k\) Program Guidance](#), and consistent with 21 CFR
320 807.92(b)(1), 510(k) Summaries shall include a brief discussion of the nonclinical tests
321 submitted, referenced, or relied on in the premarket notification submission for a determination
322 of substantial equivalence.
323

324 FDA recommends that submitters include a narrative explaining their selection of the predicate
325 device(s) used in support of the 510(k) submission in their draft 510(k) Summary submitted with
326 their original 510(k).³⁶ FDA recommends this narrative include a discussion of how the best
327 practices described in Section V of this guidance were used to select the predicate device(s)
328 proposed for use in the 510(k) submission. This recommendation is intended to promote
329 transparency to the public regarding the process of selecting a predicate device using these best
330 practices.
331

332 When a submitter cannot identify a valid predicate device(s) that is consistent with any of the
333 best practices discussed in Section V of this guidance, FDA recommends that the submitter

³⁵ As specified in 21 CFR 807.87(h), a 510(k) Statement as described in 21 CFR 807.93 may be provided in lieu of a 510(k) Summary. However, in order to facilitate transparency, FDA encourages all submitters to utilize the 510(k) Summary option.

³⁶ As described in Appendix C of the [510\(k\) Program Guidance](#), this information is provided in the Comparison of Technological Characteristics with the Predicate Device of the 510(k) Summary.

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334 include a statement in their 510(k) Summary that a valid predicate that is consistent with the best
335 practices was not available. FDA recommends that the submitter also use the Performance Data
336 Section of the 510(k) Summary to describe the ways performance testing was conducted to
337 address any known safety or effectiveness concerns with the predicate device used to support the
338 510(k) submission.³⁷
339

340 **VII. Examples**

341 The following are illustrative examples that are intended to exemplify how the best practices
342 identified in Section V of this guidance for selecting a valid predicate device can be used. These
343 examples do not necessarily account for every possible detail, risk, or consideration that a
344 submitter should consider when selecting the predicate device used in support of the 510(k)
345 submission. These examples also include different formats that could be used depending on the
346 number of valid predicate devices available for use to support the 510(k) submission.

347
348 **Example 1**

349 A submitter is preparing a 510(k) submission for a coronary guidewire, Guidewire X. The
350 submitter identified four valid predicate devices, all of which have the same intended use as
351 Guidewire X and any differences in technological characteristics do not raise different questions
352 of safety and effectiveness. The submitter included the following table in their 510(k)
353 submission, along with their rationale for selecting Predicate 4 as the predicate device used to
354 support their 510(k) submission:
355

³⁷ Section 518A of the FD&C Act directs FDA to establish a program to routinely and systematically assess information regarding device recalls, and to use that information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices. Consistent with the [510\(k\) Program Guidance](#), FDA believes that providing greater transparency on recalled devices is one way to help achieve this directive.

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Valid Predicate Device	A – Well-established methods	B – Meets or exceeds expected predicate performance	C – Unmitigated use-related or design-related safety issues	D – Associated design-related recall
1	Used internal methods that are not widely available and accepted	High frequency of fractures reported in MDRs/MedSun reports	Safety communication found on FDA’s website	No design-related recall identified
2	Used relevant methods that were published in the public domain	Expected frequency of reported adverse events	No known unmitigated use-related or design-related safety issues	Design-related recall identified in FDA’s database
3	Used outdated methods in a subsequently superseded FDA guidance document	Expected frequency of reported adverse events	No known unmitigated use-related or design-related safety issues	No design-related recall identified
4	Used updated methods from current FDA guidance document	Expected frequency of reported adverse events	No known unmitigated use-related or design-related safety issues	No design-related recall identified

356

357 In their draft 510(k) Summary, the submitter includes a brief narrative describing the above
358 selection process in the proposed 510(k) Summary. The submitter’s draft 510(k) Summary also
359 includes a discussion that the selected predicate used well-established methods from a current
360 FDA guidance document, discusses the frequency of reported adverse events, and states that
361 there are no known unmitigated use-related or design-related safety issues or design-related
362 recalls.

363

364 **Example 2**

365 A submitter is preparing a 510(k) submission for a bone sonometer, Bone Sonometer X. The
366 submitter identified only one valid predicate device, which has the same intended use as bone
367 sonometer X and any differences in technological characteristics do not raise different questions
368 of safety and effectiveness. The valid predicate device, Predicate 1, used the currently FDA-
369 recognized versions of applicable consensus standards, has an expected frequency of reported
370 events, had no known unmitigated use-related or design-related safety issues before submission
371 of the device-related recall, but has been associated with a design-related recall.

372

373 The submitter referenced Predicate 1 as their predicate device in their 510(k) submission, along
374 with a statement that Predicate 1 was the only valid predicate device that could be identified. The
375 submitter also described the ways performance testing was conducted to address the safety

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376 concerns relevant to the design-related recall associated with Predicate 1 and the measures taken
377 to mitigate those safety concerns in the subject device.

378
379 In their draft 510(k) Summary, the submitter identified that the predicate device used to support
380 the 510(k) submission has been the subject of a design-related recall, but also included a brief
381 narrative describing the selection process in the proposed 510(k) Summary. The sponsor also
382 included a summary of how their performance testing provided in the 510(k) addressed the safety
383 concerns relevant to Predicate 1’s design-related recall in the Performance Data section of the
384 draft 510(k) Summary.

Example 3

387 A submitter is preparing a 510(k) submission for an intervertebral fusion device (IFD), IFD X.
388 The submitter identified two valid predicate devices, both of which have the same intended use
389 as IFD X and any differences in technological characteristics do not raise different questions of
390 safety and effectiveness. Predicate 1 has been on the market for 15 years and Predicate 2 has
391 been on the market for 3 years and both devices are still in clinical use. The submitter included
392 the following table in their 510(k) submission, along with their rationale describing that while
393 Predicate 2 also uses the best practices for selecting a predicate device, Predicate 1 was selected
394 as the predicate device used to support the 510(k) submission because it has a well-established
395 safety profile due to a longer duration of device use.

Valid Predicate Device	A – Well-established methods	B – Meets or exceeds expected predicate performance	C – Unmitigated use-related or design-related safety issues	D – Associated design-related recall
1	Used relevant methods that were published in the public domain	Expected frequency of reported adverse events. History of safe use established due to duration of device on the market.	No known unmitigated use-related or design-related safety issues	No design-related recall identified
2	Used relevant methods that were published in the public domain	Expected frequency of reported adverse events	No known unmitigated use-related or design-related safety issues	No design-related recall identified

397
398 In their draft 510(k) Summary, the submitter includes a brief narrative describing the above
399 selection process in the proposed 510(k) Summary. The submitter’s draft 510(k) Summary also
400 includes a discussion that the predicate used to support the 510(k) submission used well-
401 established methods for IFDs, discusses the frequency of reported adverse events, including that
402 the device has a well-established safety profile through a history of safe use due to its longer
403 duration on the market, and states that there are no known unmitigated use-related or design-
404 related safety issues or associated design-related recalls.