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Remanufacturing of Medical Devices

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

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Preface

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I. Introduction

Medical devices encompass a vast array of products with different technologies, product lifecycles, complexity, intended users, and environments of use. Many devices are reusable and need preventive maintenance and repair during their useful life. For these devices, proper servicing is critical to their continued safe and effective use. However, there is a lack of clarity regarding the distinction between “servicing” and “remanufacturing” of a device. Most notably, remanufacturing has implications for the regulatory responsibilities of entities performing these activities.¹

This draft guidance is intended to help clarify whether activities performed on devices are likely “remanufacturing.” Such clarification is intended to help provide consistency and better understanding of applicable statutory and regulatory requirements. This draft guidance also includes recommendations for information that should be included in labeling to help assure the continued quality, safety, and effectiveness of devices that are intended to be serviced over their useful life. In drafting this guidance, FDA considered objective evidence and information learned from the Agency’s activities discussed in this draft guidance.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the [FDA Recognized Consensus Standards Database](#).² For more information regarding use of consensus standards in regulatory submissions, please refer to the FDA guidance titled “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical](#)

¹ FDA’s [Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices](#) (FDA Report on Device Servicing) discusses medical device servicing in more detail. Available at <https://www.fda.gov/media/113431/download>.

² Available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>.

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32 [Devices](#)³ and “[Standards Development and the Use of Standards in Regulatory Submissions](#)
33 [Reviewed in the Center for Biologics Evaluation and Research.](#)”⁴

34
35 The contents of this document do not have the force and effect of law and are not meant to bind
36 the public in any way, unless specifically incorporated into a contract. This document is intended
37 only to provide clarity to the public regarding existing requirements under the law. FDA
38 guidance documents, including this guidance, should be viewed only as recommendations, unless
39 specific regulatory or statutory requirements are cited. The use of the word should in Agency
40 guidance means that something is suggested or recommended, but not required.

41

42 **II. Background**

43 **A. FDA activities**

44 FDA has been working to gain additional perspectives on the distinction between “servicing”
45 and “remanufacturing” and has undertaken several efforts to help promote clarity. FDA opened a
46 docket for public comment⁵ and held a public workshop in 2016.⁶ FDA received comments,
47 complaints, and adverse event reports alleging inadequate servicing, which were discussed and
48 analyzed in the [FDA Report on Device Servicing](#),⁷ published by FDA in May 2018 in
49 accordance with section 710 of the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115-
50 52).⁸

51

52 In the FDA Report on Device Servicing, FDA concluded that a majority of the comments,
53 complaints, and adverse event reports received by the Agency that referred to inadequate
54 “servicing” causing or contributing to adverse events and deaths actually pertained to
55 “remanufacturing.” This conclusion was based on FDA’s evaluation of the available objective
56 evidence⁹ related to the quality, safety, and effectiveness of medical device servicing.

57

58 In 2018, FDA released a white paper, opened a public docket, and held a public workshop to
59 facilitate public discussion on the distinction between servicing and remanufacturing.¹⁰ The

³ Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>.

⁴ Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/standards-development-and-use-standards-regulatory-submissions-reviewed-center-biologics-evaluation>.

⁵ 81 FR 11477. Public comments submitted to the docket are searchable under FDA-2016-N-0436, available at <https://www.regulations.gov/docket?D=FDA-2016-N-0436>.

⁶ 81 FR 46694.

⁷ Available at <https://www.fda.gov/media/113431/download>.

⁸ FDA’s conclusions in this report were based on the available information, which included but was not limited to the information presented at the 2016 public workshop, responses to the docket request for comments, and evaluation of objective evidence related to the quality, safety, and effectiveness of medical device servicing.

⁹ The objective evidence evaluated in the FDA Report on Device Servicing included a numerical estimation of service and repair entities, literature review, ECRI Institute analysis, medical device reports (MDR), and complaints that FDA received.

¹⁰ Available at <https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-workshop-medical-device-servicing-and-remanufacturing-activities-december-10-11-2018-12102018>. FDA requested comments through docket number FDA-2018-N-3741.

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60 white paper described FDA’s initial thoughts about guiding principles, provided a flowchart with
61 accompanying text for understanding the distinctions, and contained a complementary approach
62 for software, as well as considerations for labeling, and examples utilizing the flowchart. FDA
63 also included targeted questions throughout the white paper for which the Agency sought
64 feedback. FDA considered the comments from the public docket and discussions during the
65 public workshop in developing this draft guidance.
66

B. FDA’s current thinking

68 The distinction between “remanufacturing” and “servicing” is important to understand.
69 Remanufacturing is the processing, conditioning, renovating, repackaging, restoring, or any other
70 act done to a finished device that significantly changes the finished device’s performance or
71 safety specifications, or intended use.¹¹ For the purposes of this guidance, we refer to the original
72 equipment manufacturer’s (OEM’s) legally marketed finished device as the “legally marketed
73 device.”
74

75 Servicing is the repair and/or preventive or routine maintenance of one or more parts in a
76 finished device, after distribution, for purposes of returning it to the safety and performance
77 specifications established by the OEM and to meet its original intended use.¹² As described in
78 the FDA Report on Device Servicing, FDA’s authority to regulate the servicing of medical
79 devices by any entity is grounded in the Agency’s authority to regulate medical devices and
80 radiation-emitting electronic products under the Federal Food, Drug, and Cosmetic (FD&C) Act.
81

82 Irrespective of an entity’s self-identified designation as a “servicer” or “remanufacturer,” FDA
83 focuses on the specific activities an entity performs on a particular device.¹³ The determination
84 of whether the activities an entity performs are remanufacturing affects the applicability and
85 enforcement of regulatory requirements under the FD&C Act and its implementing regulations.
86 FDA has consistently enforced requirements under the FD&C Act and its implementing
87 regulations on entities engaged in remanufacturing, including but not limited to registration and
88 listing, adverse event reporting, the Quality System (QS) regulation, and marketing submissions.
89

III. Scope

91 Because of the apparent confusion between servicing and remanufacturing among entities
92 performing these activities, FDA committed in the FDA Report on Device Servicing to issue
93 guidance that clarifies the difference between servicing and remanufacturing activities. To assist

¹¹ See 21 CFR 820.3(w).

¹² For purposes of the report that Congress required FDA to post on its website, section 710(c) of FDARA (Pub. L. 115-52, 131 Stat. 1068) defines servicing to include, “with respect to a device, refurbishing, reconditioning, rebuilding, remarketing, repairing, remanufacturing, or other servicing of the device.” However, for purposes other than this report, FDA does not consider remanufacturing to be a type of servicing.

¹³ The designations of servicer and remanufacturer are not mutually exclusive. The same entity may meet the definition of either designation based on their activities on one or multiple devices.

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94 with this clarification, FDA focuses this draft guidance on those activities that are likely
95 remanufacturing.

96
97 This draft guidance addresses activities performed on devices that are intended to be reused and
98 maintained. This draft guidance discusses whether activities performed by OEMs and third
99 parties on such devices are likely remanufacturing. This draft guidance is not intended to adopt
100 significant policy changes, but to clarify FDA’s current thinking on applicable definitions, and
101 clarify, not change, the regulatory requirements applicable to remanufacturers. The concepts in
102 this draft guidance are also not intended to alter or supersede existing regulations and policies
103 related to the regulatory threshold for submitting a marketing submission for a device.

104
105 The products included within the scope of this guidance are devices as defined in section 201(h)
106 of the FD&C Act, including software and electronic products that meet the definition of a device.
107 In general, the concepts discussed in this guidance are meant to apply to all reusable devices,
108 irrespective of their classification into class I, II, or III, including those subject to premarket
109 approval. This guidance is not intended to address reprocessed single-use devices.

110

111 **IV. Definitions**

112 The following definitions apply for the purposes of this guidance.¹⁴

- 113
- 114 • **Manufacturers (Manufacturers, OEMs, or Remanufacturers)**: A manufacturer is any
115 person who designs, manufactures, fabricates, assembles, or processes a finished
116 device.¹⁵ A remanufacturer is any person who processes, conditions, renovates,
117 repackages, restores, or does any other act to a finished device that significantly
118 changes the finished device’s performance or safety specifications, or intended use.¹⁶
119 Remanufacturers are considered to be manufacturers.¹⁷ For electronic products, a
120 manufacturer is any person engaged in the business of manufacturing, assembling, or
121 importing electronic products.¹⁸
 - 122 • **Intended use**: The general purpose of the device or its function, which encompasses
123 the indications for use.¹⁹
 - 124 • **Performance specifications**: The performance characteristics of a device established
125 by the OEM for the device to perform as intended, including those listed in device
126 labeling or in finished product release specifications. Some examples include
127 measurement accuracy, output accuracy, energy output level, and stability criteria.
 - 128 • **Recondition/Refurbish/Rebuild**: Restores a medical device to the OEM’s original
129 specifications or to be “like new.” The device may be brought to current
130 specifications if the change(s) made to the device do not significantly change the
finished device’s performance or safety specifications, or intended use. These

¹⁴ Consistent with FDA’s current thinking in this context, some of the definitions that appeared in the FDA Report on Device Servicing have been modified to reflect updated understanding and practice.

¹⁵ 21 CFR 820.3(o).

¹⁶ 21 CFR 820.3(w).

¹⁷ 21 CFR 820.3(o) and 820.3(w).

¹⁸ 21 CFR 1000.3(n).

¹⁹ FDA uses this term consistent with the meaning of intended uses in 21 CFR 801.4.

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- 131 activities include repair of components, installation of OEM provided updates and
132 upgrades, and replacement of worn parts.
- 133 • Remanufacture: Process, condition, renovate, repackage, restore, or any other act
134 done to a finished device that significantly changes the finished device’s performance
135 or safety specifications, or intended use.²⁰
 - 136 • Repair: A type of servicing that returns a component to original specifications,
137 including replacing non-working components or parts outside of routine or periodic
138 upkeep for the current owner of the device.
 - 139 • Reprocessing: With respect to reusable devices, means validated processes used to
140 render a medical device, which has been previously used or contaminated, fit for a
141 subsequent single use on a patient. These processes are designed to remove soil and
142 contaminants by cleaning and to inactivate microorganisms by disinfection or
143 sterilization.²¹
 - 144 • Safety specifications: The safety characteristics of a device established by the OEM
145 for the safe use of the device, including those incorporated into the device design and
146 finished product release specifications, generally including the device’s compensating
147 controls and risk mitigations. Some examples include alarms, sensors, and locking or
148 fail-safe mechanisms.
 - 149 • Service: Repair and/or preventive or routine maintenance of one or more parts in a
150 finished device, after distribution, for purposes of returning it to the safety and
151 performance specifications established by the OEM and to meet its original intended
152 use. Servicing excludes activities that significantly change the finished device’s
153 safety or performance specifications, or intended use.
 - 154 • Third party servicers and Independent Service Organizations (ISOs): Entities, other
155 than the OEM or healthcare delivery organizations, that maintain, restore, refurbish,
156 or repair a finished device after distribution, for purposes of returning it to the safety
157 and performance specifications established by the OEM and to meet its original
158 intended use.
 - 159

160 V. Guiding Principles

161 In using this guidance to help determine whether activities are remanufacturing, FDA
162 recommends application of the following guiding principles:

- 163
- 164 1. **Assess whether there is a change to the intended use** – Given that the purpose of
165 servicing is to return the device to the safety and performance specifications established
166 by the OEM and to meet its original intended use, any change to the intended use should

²⁰ 21 CFR 820.3(w).

²¹ See the FDA guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling,” available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling>.

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- 167 be evaluated to determine whether the activity is remanufacturing.²²
168
169 2. **Determine whether the activities, individually and cumulatively, significantly**
170 **change the safety or performance specifications of a finished device** – Under 21 CFR
171 820.3(w), remanufacturing includes activities that significantly change the performance
172 or safety specifications of the finished device. FDA considers “change” to also include
173 activities that improve the device. Activities that are not *intended to* significantly change
174 the performance or safety specifications, however, should still be evaluated to determine
175 whether they *do* significantly change the finished device’s performance and safety
176 specifications. Multiple changes, when considered cumulatively, may significantly
177 change the performance or safety specifications of the legally marketed device and
178 should be evaluated.
179
180 3. **Evaluate whether any changes to a device require a new marketing submission** –
181 Regardless of whether changes made to a legally marketed device are remanufacturing,
182 such changes should be evaluated to determine whether a premarket notification (510(k))
183 or other marketing submission is required pursuant to the FD&C Act and applicable
184 regulations, and entities should consult relevant guidance for FDA’s recommendations on
185 the topic.²³ For example, a change to a device subject to 510(k) and/or special controls
186 should be considered with respect to the criteria in 21 CFR 807.81 describing when a new
187 510(k) submission is required and any special controls under the relevant device
188 classification regulation, respectively.
189
190 4. **Assess component/part/material²⁴ dimensional and performance specifications** –
191 Assessment of changes to dimensional and performance specifications can inform
192 whether the activity performed is remanufacturing. The impact of
193 component/part/material changes can be evaluated by comparison to the OEM
194 components/parts/materials specifications and/or through verification and validation
195 testing. Deviations in component/part/material specifications from the OEM’s legally
196 marketed device may result in significant changes to the device’s performance or safety
197 specifications, and may necessitate closer evaluation (such as conducting testing or a
198 risk-based assessment) and consideration of the regulatory criteria describing when a new
199 marketing submission is required.
200

²² Consistent with Guiding Principle 3, any changes that affect or change intended use should be considered pursuant to applicable regulations.

²³ See, e.g., “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 “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>, for FDA’s current thinking on this topic.

²⁴ 21 CFR 820.3(c) defines a component as any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device. In this guidance, “component” and “component/part/material” are used interchangeably. Due to the nature of software and firmware, consideration of whether activities involving them may be remanufacturing is discussed separately from components/parts/materials.

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- 201 5. **Employ a risk-based approach** – Entities should employ a risk-based approach, such as
202 one that conforms to or is consistent with ISO 14971: *Medical devices – Application of*
203 *risk management to medical devices* when assessing whether an activity they perform is
204 remanufacturing. For the purposes of this guidance, a risk-based assessment is based on
205 the combination of multiple risk concepts that are important for managing the risks of
206 medical devices. Risk estimation, risk acceptability, risk control, benefit/risk analysis,
207 assessment of hazards and hazardous situations, and overall risk evaluation are all
208 concepts that can be applied during these activities. The concept of risk, as defined in
209 ISO 14971, is the combination of the probability of occurrence of harm and the severity
210 of that harm. Although the risk terminology used in this document is primarily derived
211 from ISO 14971, we recognize that an individual entity’s terminology may differ.

212
213 For the purposes of this guidance, a new risk is a new hazard or hazardous situation that
214 did not exist for the legally marketed device. An activity performed on a device may
215 introduce a new risk, or may modify the probability or severity of a known risk. An
216 activity is likely remanufacturing when a risk-based assessment identifies any new risks
217 or significant modifications to known risks, as these are likely to significantly change
218 performance or safety specifications, in comparison to the legally marketed device.

- 219
220 6. **Adequately document decision-making** – When deciding whether an activity is
221 remanufacturing or not, FDA recommends that the rationale for the determination be
222 documented in sufficient detail, including reference to supporting verification and
223 validation data, to explain how the determination was made. Specifically, such
224 documentation should specify why the activities performed on the device do or do not
225 significantly change the performance or safety specifications, or intended use of the
226 legally marketed device. If an entity previously determined that an activity was not
227 remanufacturing, and the same entity is performing the identical activity on the same
228 version or model of a device, such documentation could reference previous
229 determinations. Effective documentation can facilitate sound decision-making and
230 evaluation of relevant factors and information such as adverse events, and provide
231 important information for an entity to help justify their decision-making in the event that
232 an inspection is conducted by FDA or this information is otherwise requested.

234 **VI. Relevant considerations to determine if activities are** 235 **remanufacturing**

236 **A. What is a significant change to device performance or** 237 **safety specifications?**

238 Remanufacturing is the processing, conditioning, renovating, repackaging, restoring, or any other
239 act done to a finished device that significantly changes the finished device’s performance or
240 safety specifications, or intended use.²⁵ For purposes of this draft guidance, FDA generally

²⁵ 21 CFR 820.3(w).

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241 considers a significant change to device performance or safety specifications to be one that,
242 based on verification and validation testing and/or a risk-based assessment, results in a finished
243 device that is outside the OEM’s performance or safety specifications or introduces new risks or
244 significantly modifies existing risks. For example, a change to a material that contacts the human
245 body and impacts the adequacy of the OEM’s validated reprocessing instructions is likely a
246 significant change to device performance or safety specifications, and therefore, is likely
247 remanufacturing. Conversely, replacing an internal capacitor with one that has the same
248 specifications (e.g., same capacitance, working voltage, temperature range, and footprint) is not
249 likely to significantly change device performance or safety specifications and therefore, is likely
250 not remanufacturing.

251
252 FDA has identified certain types of activities that, in general, the Agency believes significantly
253 change the legally marketed device’s performance or safety specifications:

- 254 • Changes to the device’s sterilization methods;
- 255 • Changes to the device’s reprocessing instructions;²⁶ and
- 256 • Changes to the device’s control mechanism,²⁷ operating principle,²⁸ or energy type.²⁹

257
258 As discussed below in Section VI.B, activities that result in these changes are likely
259 remanufacturing, and evaluation using the flowchart and accompanying text is not
260 recommended.

261
262 Remanufacturing also includes significant changes to a device’s intended use (e.g., changing a
263 single-use device to become reusable, changing the anatomical location of use).³⁰ Therefore, as
264 discussed in Guiding Principle 1, any change to the intended use should be evaluated to
265 determine whether the activity is remanufacturing.

266

267 **B. Determining whether activities are “remanufacturing”**

268 For activities involving components/parts/materials, FDA recommends the use of the flowchart
269 in this section (Figure 1) to help entities determine if their activities are likely remanufacturing.
270 Although the servicing and remanufacturing definitions and guiding principles in this document
271 apply to software, the approach described in this section should not be applied to software due to

²⁶ See the FDA guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling,” available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling>.

²⁷ For purposes of this guidance, a control mechanism is the manner by which the actions of a device are directed. One example of a control mechanism change would be a change from analog to digital control of a medical device.

²⁸ For purposes of this guidance, an operating principle is the mode of operation or mechanism of action through which a device fulfills (or achieves) its intended use. An example of a new operating principle would be changing the image reconstruction algorithm used in a computed tomography x-ray system from simple back projection to a new, more radiation-efficient method.

²⁹ For purposes of this guidance, energy type is the type of power input to or output from the device. These changes include both energy output and input changes. A change from emitting microwave energy to radiofrequency (RF) energy would be an example of an energy output change; this type of change would likely be part of a significant redesign.

³⁰ 21 CFR 820.3(w).

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272 its nature and the methods used to evaluate changes to software. Instead, see Section VII for a
273 discussion of changes involving software.

274
275 Figure 1 is a visual aid intended to be used in conjunction with the accompanying text in this
276 section and guiding principles. Figure 1 and the accompanying text in this section are intended to
277 address the most common and important considerations that should be evaluated, but is not
278 meant to capture *all* potential considerations that an entity should evaluate to determine if their
279 activities are likely remanufacturing. Rather, they are intended to guide entities in determining
280 when they should further evaluate such activities by conducting testing or a risk-based
281 assessment. Figure 1 and the accompanying text are intended to be consulted after it is
282 determined that there is no significant change to intended use.

283
284 In Figure 1, each change (e.g., physical change or change to safety control) should first be
285 assessed individually to determine whether the activity is likely remanufacturing. After
286 evaluating each change individually, the cumulative effects should be assessed to determine
287 whether the activities resulting in the collective changes are likely remanufacturing. The legally
288 marketed device should be used as the basis for comparison for individual changes and the
289 cumulative effects of such changes. When there are no deviations in component/part/material
290 dimensional or performance specifications, or intended use, from the OEM counterpart, and
291 there are no new or modified risks or change in the performance or safety specifications of the
292 legally marketed device, there would likely be no significant changes to the legally marketed
293 device, in the absence of other changes.

294
295 FDA does not recommend evaluation with Figure 1 when an activity is performed on behalf of,
296 or otherwise explicitly authorized by, the OEM **and** the activity returns the legally marketed
297 device to its original performance and safety specifications, and intended use. FDA believes such
298 activities would likely not be remanufacturing, and the determination should be adequately
299 documented.

300
301 Entities performing activities on devices should make a determination about whether each
302 activity and the cumulative effects of such activities are remanufacturing and document their
303 rationale.³¹ When deciding whether an activity is remanufacturing, entities should document the
304 decision-making process and the basis for the determination. The documentation should be
305 prepared in a way that an FDA investigator or other third party can understand what the change
306 was and the rationale underlying the conclusion. For this, we recommend that the documentation
307 include, at a minimum, the following:³²

- 308 • Product name (including model number and serial number, if applicable);
- 309 • Date of activities performed, assessment, and determination;
- 310 • Description of device;

³¹ In addition, FDA notes that under 21 CFR Part 820, manufacturers are required to maintain certain records as applicable, e.g., service reports.

³² Consistent with Guiding Principle 6, if the identical activity was previously determined to not be remanufacturing, is being performed by the same entity, and is being performed on the same version or model of a device, such documentation could reference previous determinations.

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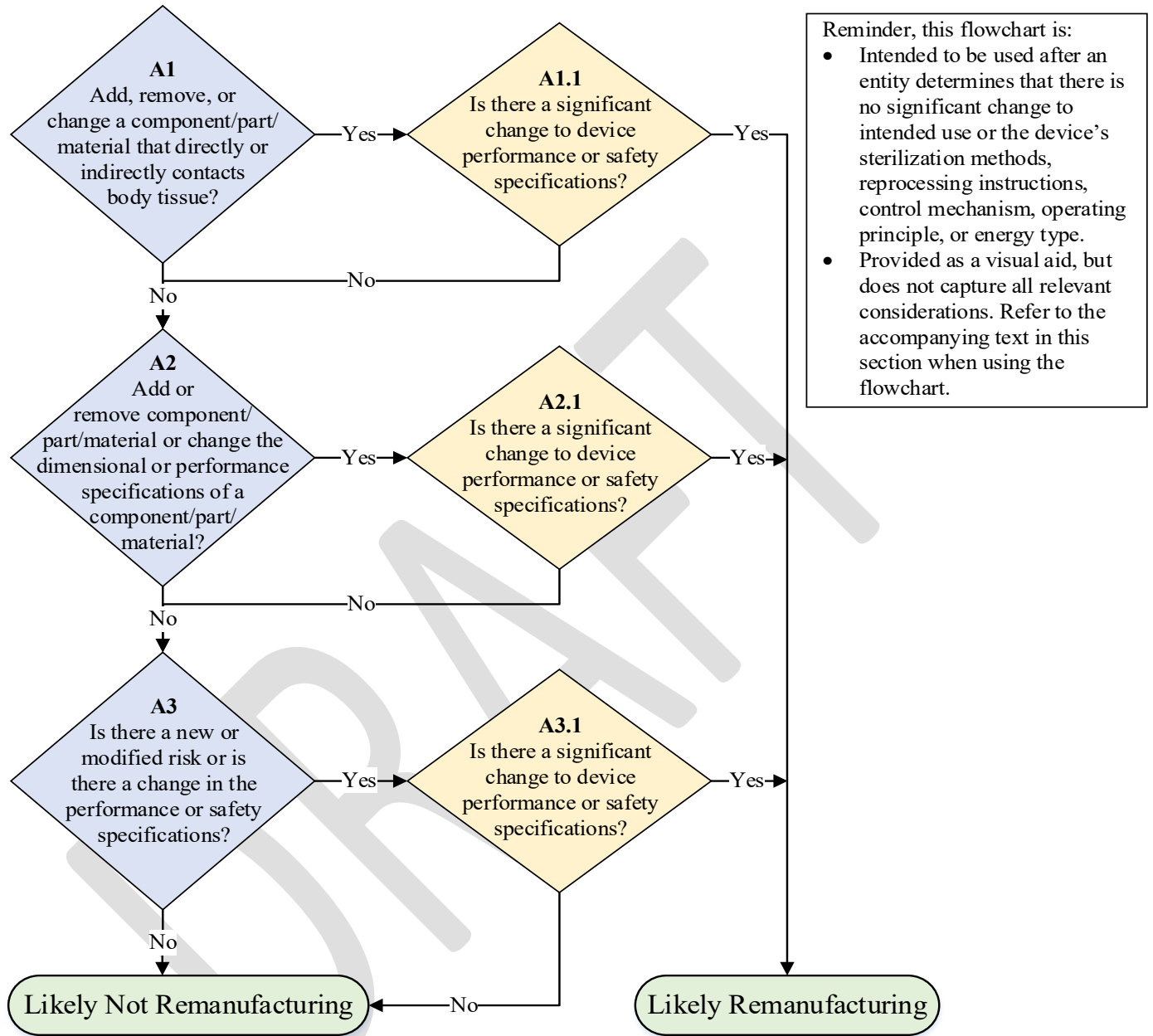
- 311 • Description of activities to be performed, including documentation of
- 312 components/parts/materials involved;
- 313 • Determination of whether the activity is remanufacturing (we recommend using the
- 314 applicable sections of this guidance);
- 315 • Reference to related documents supporting the decision-making process; and
- 316 • Signature(s).

317
318 FDA has included examples of such documentation in Appendix B.

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319 **Figure 1.** Flowchart to help determine whether activities performed are likely remanufacturing.

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320 **A1. Add, remove, or change a component/part/material that directly or** 321 **indirectly contacts body tissue?**

322 Consistent with FDA’s guidance documents on reprocessing³³ and biocompatibility,³⁴
323 respectively, entities should assess how their activities may affect validated reprocessing
324 instructions or cause an unacceptable adverse biological response resulting from device contact
325 with the human body, including both patient and healthcare provider tissue.

326
327 Direct contact is when a component/part/material comes into physical contact with body tissue,
328 such as catheter tubing used on a patient. A component/part/material has indirect contact when a
329 fluid or gas passes through it prior to the fluid or gas coming into physical contact with body
330 tissue (i.e., the device or component/part/material itself does not physically contact body tissue).
331 For example, materials in a catheter hub (the part of the catheter that is external to the patient)
332 indirectly contact the patient when fluids or drugs are infused through the hub and into the
333 patient. Both direct and indirect contact with the patient or user of the device should be
334 considered when answering A1.

335
336 If there is any addition, removal, or change to a component/part/material on the finished device,
337 and that component/part/material directly or indirectly contacts body tissue, the answer to A1
338 should be “yes.” This includes exposing a previously unexposed component/part/material to
339 direct or indirect contact with body tissue. Additionally, if there is any change in material type,
340 formulation, or chemical composition for a component/part/material that directly or indirectly
341 contacts body tissue, the answer to A1 should be “yes.” If the entity is uncertain how to respond
342 to A1, the answer should be “yes.” A “yes” answer to A1 does not necessarily mean that the
343 activity is remanufacturing. Rather, when an entity makes such changes, it should analyze the
344 impact of the change on the device’s performance and safety specifications using the text in
345 A1.1.

346
347 If no component/part/material added, removed, or changed directly or indirectly contacts body
348 tissue, the answer should be “no” and then proceed to A2.

349 **A1.1 Is there a significant change to device performance or safety** 350 **specifications?**

351 If the activity adds, removes, or changes a component/part/material that directly or indirectly
352 contacts body tissue (as mentioned above, this includes an activity that exposes a previously
353 unexposed component/part/material to body tissue either directly or indirectly), a risk-based
354 assessment should be conducted. The assessment should be conducted to determine whether
355 there is a significant change to the biocompatibility or the validated reprocessing instructions of

³³ See the FDA guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling,” available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling>.

³⁴ See the FDA guidance “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,’” available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and>.

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356 the legally marketed device. An activity that results in such change may be considered
357 remanufacturing.

358
359 Depending on the magnitude of the change and the nature of the component/part/material,
360 reprocessing validation and a comprehensive biocompatibility risk assessment or testing may be
361 necessary. Entities should incorporate factors that affect the reprocessing and biocompatibility of
362 a device in their risk-based assessment and testing where appropriate. These factors may include
363 the materials of construction, the processing of the materials, methods (including the sterilization
364 process), any residuals from aids used during the process, and intended use life of the legally
365 marketed device. Activities that impact the adequacy of the legally marketed device’s validated
366 reprocessing instructions are likely remanufacturing.

367
368 If the answer to A1.1 is “yes,” then the activity would likely be remanufacturing. If the answer to
369 A1.1 is “no,” then proceed to A2.

A2. Add or remove component/part/material or change the dimensional or performance specifications of a component/part/material?

370 *Add or remove component/part/material?* If there is any addition of a component/part/material to
371 a legally marketed device that was not originally part of the legally marketed device, the answer
372 to A2 should be “yes.” Examples include adding an adhesive to mend a break in the device or
373 fasteners to secure a component/part/material. If there is any removal of a
374 component/part/material to a legally marketed device that is not replaced in the legally marketed
375 device, the answer to A2 should be “yes.” Examples include removing a fastener or barrier
376 without replacement. Add or remove component/part/material also includes replacing an OEM
377 component/part/material with the same OEM component/part/material or a non-OEM
378 component/part/material.³⁵

379
380
381 *Change the dimensional or performance specifications of a component/part/material?* If there is
382 any change to or replacement of a component/part/material of the legally marketed device, which
383 affects the component/part/material’s dimensional or performance specifications, the answer to
384 A2 should be “yes.”

385
386
387 If a component/part/material is not being added or removed, or the dimensional or performance
388 specifications of a component/part/material are not being changed, the answer to A2 should be
389 “no.” If uncertain, the answer to A2 should be “yes.”

390
391 A “yes” answer to A2 does not necessarily mean that the activity is remanufacturing. Rather,
392 when an entity makes such changes, it should analyze the impact of the change on the device’s
393 performance and safety specifications using the text in A2.1. If the answer to A2 is “no,” then
394 proceed to A3.

³⁵ As discussed above in Section VI.B., FDA does not recommend evaluation with Figure 1 when an activity is performed on behalf of, or otherwise explicitly authorized by, the OEM and the activity returns the legally marketed device to its original performance and safety specifications, and intended use. FDA believes such activities would likely not be remanufacturing, and the determination should be adequately documented.

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395 **A2.1 Is there a significant change to device performance or safety** 396 **specifications?**

397 *Does the added or removed component/part/material significantly change the device*
398 *performance or safety specifications?* When evaluating whether the addition or removal of a
399 component/part/material significantly changes the device’s performance or safety specifications,
400 the entity should consider the intended use life of the legally marketed device. For instance,
401 many reusable devices are reprocessed numerous times within their intended use life. Applicable
402 considerations should include an assessment of whether the added component will withstand
403 repeated reprocessing cycles within the device’s intended use life or whether the removed
404 component exposes previously unexposed components that will withstand repeated reprocessing
405 cycles within the device’s intended use life. Such an assessment can include verification and
406 validation testing or a risk-based assessment describing why such testing is not warranted. If the
407 reusable device will not be able to withstand repeated reprocessing cycles within its intended use
408 life, the addition or removal of the component/part/material may significantly change the legally
409 marketed device’s performance or safety specifications.

410
411 *Do the changed dimensional specifications of the component/part/material significantly change*
412 *the device performance or safety specifications?* In determining whether an activity is
413 remanufacturing for these types of changes, the entity should consider not only the magnitude of
414 the dimensional specification change, but the criticality of the modified dimension. The entity
415 should consider whether dimensional specifications meet a minimum or maximum specification
416 (e.g., outer diameter cannot exceed 3.0 mm) or are within a range of acceptable tolerance
417 specifications. If dimensional specifications are within the acceptable range, the answer to A2.1
418 would likely be “no;” however, for changes that are outside the acceptable range of dimensional
419 specifications, the answer to A2.1 would likely be “yes.”

420
421 *Do the changed performance specifications of the component/part/material significantly change*
422 *the device performance or safety specifications?* When evaluating if there is a significant change
423 to performance or safety specifications, the entity should consider whether performance outputs
424 meet a minimum and/or maximum specification (e.g., temperature within chamber cannot exceed
425 25 °C and pressure cannot be less than 150 kPa) or are within a range of acceptable tolerance
426 specifications (e.g., pump flowrate must be between 2 and 20 mL/hour). If performance
427 specifications are within the acceptable range, the answer to A2.1 would likely be “no;”
428 however, for changes that result in performance specifications that are outside the acceptable
429 range, the answer to A2.1 would likely be “yes.”

430
431 If the answer to A2.1 is “yes,” then the change would likely be remanufacturing. If the answer to
432 A2.1 is “no,” then proceed to A3.

433 **A3. Is there a new or modified risk or is there a change in the performance or** 434 **safety specifications?**

435 The entity should perform a risk-based assessment to identify new or modified risks or a change
436 in the performance or safety specifications of the legally marketed device based on the activity
437 being performed on the device. Both the individual change and cumulative changes performed

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438 on the legally marketed device should be considered. While individual changes may not
439 significantly change the legally marketed device’s performance or safety specifications, the
440 cumulative changes may do so. The extent of the assessment should be appropriate considering
441 the nature and extent of the activities being performed.
442

443 *Is there a new or modified risk?* A risk-based assessment can identify whether there are new
444 risks or modified existing risks in comparison to the legally marketed device. If a new risk is
445 created or an existing risk has been modified based on the activity being performed, the answer
446 to A3 should be “yes,” and this activity should be evaluated using the text in A3.1. If uncertain,
447 the answer to A3 should be “yes.”
448

449 *Is there a change in the performance or safety specifications?* A risk-based assessment can also
450 identify whether there is a change in performance or safety specifications. This assessment
451 should consider, for example, how a change could impact a device’s continued conformity to a
452 voluntary consensus standard or compliance with a regulation, such as special controls identified
453 in a device classification regulation. This assessment should also consider whether activities that
454 break a seal or barrier can adequately return the device to its legally marketed performance and
455 safety specifications. If a change to performance or safety specifications has been identified, the
456 answer to A3 should be “yes.” If uncertain, the answer to A3 should be “yes.”
457

458 When an entity makes a change that has a “yes” answer to A3, the entity should analyze the
459 impact of the change on the device’s performance and safety specifications using the text in
460 A3.1. If the answer to A3 is “no,” then the change is likely not remanufacturing.

A3.1 Is there a significant change to device performance or safety specifications?

463 If new or modified risks were identified, the entity should evaluate whether they significantly
464 change the legally marketed device’s performance or safety specifications using the output of the
465 risk-based assessment performed in A3. Altering or bypassing a safety feature (e.g., fuses, alerts,
466 alarms, interlocks) likely significantly changes the legally marketed device’s performance or
467 safety specifications. Changes that impact compliance with a regulation or alter conformity with
468 a voluntary consensus standard would likely significantly change the legally marketed device’s
469 performance or safety specifications and may also adulterate and/or misbrand the device.³⁶
470

471 If the answer to A3.1 is “yes,” then the change would likely be remanufacturing. If the answer to
472 A3.1 is “no,” then the change is likely not remanufacturing.
473

VII. Changes involving software

475 As described in Section VI, Figure 1 and its accompanying text should not be applied to changes
476 involving software. Many software changes are likely remanufacturing because of their impact
477 on a product’s software architecture, software requirements specifications, unresolved anomalies,

³⁶ See, e.g., sections 501(e)(2) and 502(o) of the FD&C Act.

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478 and other key characteristics. Further, because the probability of a software failure cannot be
479 determined using traditional statistical methods, the risk-based assessment approach that FDA
480 recommends in Section VI should not be applied to software changes. Instead, FDA has
481 identified certain activities performed on software that are likely not remanufacturing because
482 they generally do not significantly change the performance or safety specifications of the device:

- 483 • Activities performed on behalf of or otherwise explicitly authorized by the OEM that
484 return the legally marketed device to its performance and safety specifications, and
485 intended use;
- 486 • Implementing OEM provided updates and upgrades;
- 487 • Running software-based hardware diagnostics;
- 488 • Assessing for viruses, malware, and other cybersecurity related issues;
- 489 • Reinstalling OEM software to restore original performance and safety specifications;
- 490 • Reverting software to a previous configuration;
- 491 • Installing cybersecurity updates that are authorized by the OEM;
- 492 • Turning on or off connectivity features (e.g., Wi-Fi and Bluetooth connections) consistent
493 with OEM intended use;
- 494 • Performing data backup and recovery operations;
- 495 • Assessing software inventory;
- 496 • Collecting system logs;
- 497 • Managing user accounts; and
- 498 • Accessing diagnostic and repair information.

500 Other activities involving changes to software are likely to significantly change a device's
501 performance or safety specifications, such that the activity is likely remanufacturing. However, if
502 an entity believes that an activity involving a change to software does not significantly change a
503 device's performance or safety specifications, the entity should adequately document its
504 decision-making (see Guiding Principle 6). Any activity involving software changes that
505 significantly modifies a device's intended use would be remanufacturing.³⁷

506
507 Entities should also consider the unintended consequences and cumulative effects of any
508 software change(s). Entities performing activities on devices should make a determination about
509 whether each activity and the cumulative effects of the changes resulting from the activities are
510 remanufacturing and document their rationale.

512 **VIII. Considerations for labeling**

513 Based on publicly available information and FDA's activities discussed in Section II.A of this
514 draft guidance, FDA believes that OEMs of reusable devices intend for their devices to routinely
515 undergo both preventive maintenance and repair. It is important that such devices include
516 instructions on how to adequately return a device to its performance and safety specifications

³⁷ See 21 CFR 820.3(w).

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517 established by the OEM.³⁸ Unintentional remanufacturing can occur when entities do not have
518 the instructions necessary to return a device to its original performance and safety specifications.
519 The lack of adequate servicing instructions can also create challenges in the availability of
520 quality, safe, and effective devices.

521
522 Consistent with promoting and protecting the public health, FDA encourages OEMs, as an
523 industry best practice, to provide servicing instructions that facilitate routine maintenance and
524 repair of their reusable devices.³⁹ FDA recommends that the labeling of reusable devices include
525 the following information, as applicable, to facilitate routine device maintenance and repair:

- 526 • A description of the key performance and safety specifications;
- 527 • Critical technical or functional specifications, including:
 - 528 ○ Physical dimensions;
 - 529 ○ Electrical characteristics, including batteries (e.g., chemistry, amperage, voltage,
530 rechargeability), internal fuses, and power supply (e.g., voltage, amperage,
531 frequency); and
 - 532 ○ Device-specific performance specifications (e.g., flow rate accuracy or range,
533 humidity, temperature, wavelength).
- 534 • The recommended maintenance activities and schedule;
- 535 • Recommended routine testing and acceptance criteria to confirm that the device
536 remains within its performance and safety specifications;
- 537 • A description of error codes, alerts, and alarm features on the device;
- 538 • Precautions and warnings relevant to servicing the device; and
- 539 • Version number and release date of software.

³⁸ Section 502(f)(1) of the FD&C Act requires that labeling bear adequate directions for use. For non-prescription devices, adequate directions for use include instructions on preparing a device for use. 21 CFR 801.5(g). Prescription devices are exempt from the adequate directions for use requirement provided certain conditions are met, including that the labeling bear “information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended...” 21 CFR 801.109(c).

³⁹ FDA’s recommendations in this guidance are not intended to encourage the disclosure of trade secrets or confidential commercial information (CCI).

540 **Appendix A. Examples**

541 The following are illustrative examples of activities that may be performed on devices with
542 explanations about why such examples are or are not likely remanufacturing. Note that these
543 generalized examples do not necessarily account for every possible detail, risk, or consideration
544 that a manufacturer should evaluate, and should not be taken to mean that the changes described
545 are or are not definitively remanufacturing. Real-world decisions will depend on the specific
546 facts and circumstances, including the specific details of the changes made to the specific device.
547

548 **(1) Component/part/material activities**

549 **Example E.1**

550 **Activity:** The door of an infusion pump was bent and now pinches the administration set.
551 The flow rate accuracy fell outside the OEM's specified accuracy range. The door is replaced
552 with a non-OEM door that is marketed as compatible with this infusion pump. It has the
553 same overall dimensions and is made from a similar material of construction. However, the
554 replacement door material is more rigid than the original door.
555

556 **Relevant questions:**

557 *A1. Add, remove, or change a component/part/material that directly or indirectly contacts*
558 *body tissue?*

559 No. The existing and replacement doors do not have direct or indirect contact with the
560 patient's body tissue.
561

562 *A2. Add or remove component/part/material or change the dimensional or performance*
563 *specifications of a component/part/material?*

564 Yes, the old door was removed and replaced. While the new door is marketed as compatible,
565 all dimensions were confirmed through comparative measurement, including the hinges and
566 latch. The specific material of the original door is unknown and there is a noticeable
567 difference in flexibility that may impact the pump's performance specifications.
568

569 *A2.1 Is there a significant change to device performance or safety specifications?*

570 No. Once replaced, the door was confirmed to open and close with similar effort as the
571 original door and it was confirmed that the added rigidity did not significantly change the
572 pump's performance or safety specifications (e.g., flowrate accuracy).
573

574 *A3. Is there a new or modified risk or is there a change in the performance or safety*
575 *specifications?*

576 No. A risk-based assessment determined that there are no new or modified risks and there is
577 no change in performance or safety specifications (e.g., the change does not alter conformity
578 to a voluntary consensus standard or compliance with a regulation).
579

580 **Decision:** Not Remanufacturing.
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582 **Example E.2**

583 **Activity:** The rotor within a peristaltic infusion pump no longer functions as intended and is
584 replaced. The subject pump rotor is no longer supported by the OEM, but a comparable off-
585 the-shelf rotor is available. The dimensions of the rotor, including the individual rollers, are
586 the same; however, the material of construction of the rollers, which contact and apply
587 pressure to the administration set, appears to be stainless steel. This is different from the
588 plastic rollers in the legally marketed device.

589 **Relevant questions:**

591 *A1. Add, remove, or change a component/part/material that directly or indirectly contacts*
592 *body tissue?*

593 No. Neither the existing or replacement component directly or indirectly contact body tissue.
594 It is only in contact with the outside of the administration set.

596 *A2. Add or remove component/part/material or change the dimensional or performance*
597 *specifications of a component/part/material?*

598 Yes. The rotor was removed and replaced. Also, although the dimensional specifications of
599 the non-OEM pump rotor, including the individual rollers, are the same as the OEM rotor,
600 the roller materials are different.

602 *A2.1 Is there a significant change to device performance or safety specifications?*

603 Yes. Once the rotor was replaced, the device appears to function adequately. The change in
604 material of the rollers does not significantly change the accuracy of the flowrate across the
605 labeled flowrate range. However, a risk-based assessment identified that the change in
606 material of the rollers can affect the useful life of the administration set. The change in the
607 roller material from plastic to stainless steel increases the administration set wear and/or
608 breakage due to fatigue. Evaluation of this risk concluded that the increased fatigue on the
609 administration set is more likely to lead to patient under-dosing before the administration set
610 is intended to be replaced. This significantly changes the device's performance and safety
611 specifications.

613 **Decision:** Remanufacturing.

614 **Example E.3**

616 **a. Activity:** The gradient coil of a magnetic resonance (MR) system was damaged during an
617 imaging session and needs to be replaced. The gradient coil is replaced with a non-OEM
618 gradient coil. The maximum slew rate of the coil matches that of the OEM gradient coil;
619 however, the peak gradient strength is larger than the OEM coil.

621 **Relevant questions:**

622 *A1. Add, remove, or change a component/part/material that directly or indirectly*
623 *contacts body tissue?*

624 No. The gradient coil does not have direct or indirect contact with body tissue.

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626 *A2. Add or remove component/part/material or change the dimensional or performance*
627 *specifications of a component/part/material?*
628 Yes. The gradient coil was removed and replaced, and the new gradient coil has a larger
629 peak gradient strength.

630
631 *A2.1 Is there a significant change to device performance or safety specifications?*
632 Yes. An assessment was performed to determine the significance of the change. A
633 gradient coil with a larger peak gradient strength significantly changes the imaging
634 performance specifications (e.g., slice thickness, spatial resolution).

635
636 **Decision:** Remanufacturing.

- 637
638 **b. Activity:** The gradient coil of an MR system was damaged during an imaging session and
639 needs to be replaced. It is replaced with a non-OEM gradient coil that has different
640 dimensional specifications and coil design.

641 **Relevant questions:**

642 *In this example, the answers to flowchart questions A1 and A2 are the same as Example*
643 *E.3.a. except that for A2, the new gradient coil has different dimensional specifications*
644 *and coil design.*

645
646
647 *A2.1 Is there a significant change to device performance or safety specifications?*
648 No. The new gradient coil only differs by small changes in design and dimensional
649 specifications. There are no significant changes to the performance and safety
650 specifications (e.g., slew rate, peak gradient strength, power).

651
652 *A3. Is there a new or modified risk or is there a change in the performance or safety*
653 *specifications?*

654 No. A risk-based assessment identified no new or modified risks or change in the
655 performance or safety specifications due to this change because the non-OEM gradient
656 coil has the same hardware performance specifications (e.g., slew rate), equivalent
657 imaging performance, and meets the same safety and performance specifications (e.g.,
658 acoustic output) when compared to the OEM gradient coil.

659
660 **Decision:** Not Remanufacturing.

661 **Example E.4**

662 **Activity:** The slide heater pads on an immunohistochemistry (IHC) autostainer are worn out
663 and need to be replaced. They are replaced with an OEM part.

664 **Relevant questions:**

665
666 *A1. Add, remove, or change a component/part/material that directly or indirectly contacts*
667 *body tissue?*

668 No. The slide heater pads do not have direct or indirect contact with body tissue.
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671 *A2. Add or remove component/part/material or change the dimensional or performance*
672 *specifications of a component/part/material?*

673 Yes. The heater pad components were physically removed and replaced with new pads.

674

675 *A2.1 Is there a significant change to device performance or safety specifications?*

676 No. An assessment was performed to evaluate this replacement and identified no changes to
677 dimensions, materials, or performance or safety specifications of the pads.

678

679 *A3. Is there a new or modified risk or is there a change in the performance or safety*
680 *specifications?*

681 No. A risk-based assessment identified no new or modified risks because the slide heater
682 pads are identical to the original part from the OEM. The device now functions within its
683 functional specifications identified in the labeling. There is no change in the performance or
684 safety specifications.

685

686 **Decision:** Not Remanufacturing.

687

688 **Example E.5**

689 **Activity:** The tubing on a sample processor became kinked from use and needs to be
690 replaced. Tubing was found from the same OEM but the tubing is intended for use with a
691 different sample processor.

692

693 **Relevant questions:**

694 *A1. Add, remove, or change a component/part/material that directly or indirectly contacts*
695 *body tissue?*

696 No. There is no direct or indirect contact between the tubing and body tissue.

697

698 *A2. Add or remove component/part/material or change the dimensional or performance*
699 *specifications of a component/part/material?*

700 Yes. The tubing was removed and replaced with new tubing of a different inner diameter.

701

702 *A2.1 Is there a significant change to device performance or safety specifications?*

703 Yes. The inner diameter of the tubing is different from the legally marketed device.

704 Verification and validation testing was performed to evaluate this replacement and identified
705 significant changes to performance because different fluid characteristics (e.g., flow rate)
706 than those specified for the legally marketed device were noted with the new tubing.

707

708 **Decision:** Remanufacturing.

709

710 **Example E.6**

711 **Activity:** A tissue pre-treatment water bath was updated by replacing the heating chamber
712 with one that has a different temperature range.

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714 **Relevant questions:**

715 *A1. Add, remove, or change a component/part/material that directly or indirectly contacts*
716 *body tissue?*

717 No. The tissue specimens have been removed from the human body, are within a sealed
718 container, and neither the water bath nor heating chamber directly or indirectly contacts the
719 tissue.

720
721 *A2 Add or remove component/part/material or change the dimensional or performance*
722 *specifications of a component/part/material?*

723 Yes. The heating chamber was removed and replaced. The heating chamber's performance
724 specifications were changed because the new heating chamber has a different temperature
725 range.

726
727 *A2.1 Is there a significant change to device performance or safety specifications?*

728 Yes. The performance is significantly changed because the heating range extends beyond that
729 of the heating chamber in the legally marketed device.

730

731 **Decision:** Remanufacturing.

732

733 **Example E.7**

734 a. **Activity:** A stainless steel manual drill is intended to be used in the implantation of
735 orthopedic devices. The drill is intended to be reprocessed and reused for multiple
736 procedures. The drill was sharpened because it is dull and difficult to use. This is the first
737 time the drill has been sharpened.

738

739 **Relevant questions:**

740 *A1. Add, remove, or change a component/part/material that directly or indirectly*
741 *contacts body tissue?*

742 Yes. Sharpening the drill removes material and exposes a fresh surface that directly
743 contacts bone.

744

745 *A1.1 Is there a significant change to device performance or safety specifications?*

746 No. The drill is not coated. The material and structure of the drill that contacts body
747 tissue is uniform. A risk-based assessment concluded that removal of material due to
748 sharpening does not significantly change the biocompatibility or reprocessing.

749

750 *A2. Add or remove component/part/material or change the dimensional or performance*
751 *specifications of a component/part/material?*

752 Yes. Sharpening of the drill removes material changing the dimensions of the drill.

753

754 *A2.1 Is there a significant change to device performance or safety specifications?*

755 No. The drill was returned to its performance and safety specifications because the entity
756 sharpened the device to its labeled outer diameter and original edge profile angle.

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758 *A3. Is there a new or modified risk or is there a change in the performance or safety*
759 *specifications?*

760 Yes. Sharpening the drill may change the size of the resulting pilot drill hole. Changing
761 the size of the pilot hole can change the fit of the implant or overall purchase in bone
762 such that the mechanical integrity of the implant is compromised.

763
764 *A3.1 Is there a significant change to device performance or safety specifications?*

765 No. Based on the facility's maintenance record, it was determined that this is the first
766 drill sharpening. The drill produces the same pilot hole size as the legally marketed
767 device after the sharpening has been completed. There is no significant change to the
768 device's performance or safety specifications at this time.

769
770 **Decision:** Not Remanufacturing.

771
772 b. **Activity:** A stainless steel manual drill with a titanium nitride coating is intended to be
773 used in the implantation of orthopedic devices. The drill is intended to be reprocessed and
774 reused for multiple procedures. The drill was sharpened because it is dull and difficult to
775 use. The drill has been sharpened multiple times.

776
777 **Relevant questions:**

778 *A1. Add, remove, or change a component/part/material that directly or indirectly*
779 *contacts body tissue?*

780 Yes. Sharpening the drill removes material and exposes a fresh surface that directly
781 contacts bone.

782
783 *A1.1 Is there a significant change to device performance or safety specifications?*

784 No. While sharpening the drill exposes the stainless steel surface beneath the coating,
785 both the surface coating and underlying stainless steel have been subjected to a
786 biocompatibility assessment. Additionally, a risk-based assessment concluded that
787 removal of material due to sharpening does not significantly change the biocompatibility
788 or reprocessing.

789
790 *A2. Add or remove component/part/material or change the dimensional or performance*
791 *specifications of a component/part/material?*

792 Yes. Sharpening of the drill removes material changing the dimensions and cutting
793 surface of the drill.

794
795 *A2.1 Is there a significant change to device performance or safety specifications?*

796 Yes. Based on the facility's maintenance record, it was determined that the drill has been
797 sharpened multiple times. While the outer diameter of the drill is not significantly
798 changed from the legally marketed device, the titanium nitride coating is no longer intact
799 on the cutting surface of the drill, causing inefficient or destructive cutting. This activity
800 significantly changes the device's performance and safety specifications.

801
802 **Decision:** Remanufacturing.

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Example E.8

- a. **Activity:** The lens of an endoscope is cracked. The lens is affixed by an epoxy that is not described in the labeling. The cracked lens was removed and replaced. The epoxy used was purchased from the OEM and is identical to that used in the legally marketed device. The replacement lens was not purchased from the OEM. The lens was tested and demonstrated to have the same optical specifications (e.g., focal length, Abbe number) and materials as the original lens.

Relevant questions:

A1. Add, remove, or change a component/part/material that directly or indirectly contacts body tissue?

Yes, both the lens and the epoxy directly contact body tissue.

A1.1 Is there a significant change to device performance or safety specifications?

No. The epoxy is identical to the epoxy used in the legally marketed device. The replacement lens is the same material as original lens. A risk-based assessment that considered both the individual and cumulative changes was performed to determine if the procedure used to replace the lens affects biocompatibility and reprocessing instructions. A biocompatibility assessment confirmed that there are no new surfaces previously unexposed to body tissue. A comprehensive reprocessing risk assessment and testing demonstrated that the validated reprocessing instructions identified in the labeling of the legally marketed device are not impacted by the replacement parts or the procedure used to replace the parts.

A2. Add or remove component/part/material or change the dimensional or performance specifications of a component/part/material?

Yes. The epoxy and lens were replaced.

A2.1 Is there a significant change to device performance or safety specifications?

No. The optical performance testing (e.g., resolution and distortion) and reprocessing risk assessment and testing indicated there has been no significant change in performance or safety specifications.

A3. Is there a new or modified risk or is there a change in the performance or safety specifications?

No. A risk-based assessment was performed that considered both the individual and cumulative changes that could have affected biocompatibility, reprocessing, and optical performance. This assessment identified that there are no new or modified risks, and there is no change in performance or safety specifications.

Decision: Not Remanufacturing.

- b. **Activity:** The lens of an endoscope is cracked. The lens is affixed by an epoxy that is not described in the labeling. The cracked lens was removed and replaced. The epoxy used

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848 was purchased from the OEM and is identical to that used in the legally marketed device.
849 The replacement lens comes from a different endoscope model from the same OEM; that
850 model was 510(k)-cleared with improved optical performance (e.g., resolution and
851 distortion) relative to the original endoscope. The replacement lens has the same material
852 but different optical specifications (e.g., focal length, Abbe number) from the original.
853

Relevant questions:

854 *In this example, the answers to flowchart questions A1, A1.1, and A2 are the same as*
855 *Example E.8.a.*
856

857
858 *A2.1 Is there a significant change to device performance or safety specifications?*

859 Yes. The epoxy is identical to that used in the legally marketed device, but the lens has
860 different optical specifications from the original lens. The endoscope with the
861 replacement lens has different imaging specifications relative to the legally marketed
862 device. While the replacement lens is present on another 510(k)-cleared device, it was not
863 present on the original endoscope and significantly changes the performance
864 specifications of the original endoscope.
865

866 **Decision:** Remanufacturing.
867

Example E.9

868
869 **Activity:** An endoscope's connection to the video processor was damaged during use. After
870 repair, it was observed that the endoscope readily disconnected from the video processor. To
871 address this problem, an adapter was added to reduce the probability of a disconnection
872 between the endoscope and video processor. The adapter was found to be capable of
873 connecting to the video processor; however, it is bulkier than the connector.
874

Relevant questions:

875
876 *A1. Add, remove, or change a component/part/material that directly or indirectly contacts*
877 *body tissue?*

878 No. The added adapter does not directly or indirectly contact body tissue.
879

880 *A2. Add or remove component/part/material or change the dimensional or performance*
881 *specifications of a component/part/material?*

882 Yes, the adapter has been added to the endoscope.
883

884 *A2.1 Is there a significant change to device performance or safety specifications?*

885 No. The adapter still allows the endoscope to be connected to the video processor and optical
886 performance testing demonstrated the same optical performance as the original endoscope.
887

888 *A3. Is there a new or modified risk or is there a change in the performance or safety*
889 *specifications?*

890 Yes. A risk-based assessment was performed to determine the effects of this added
891 component. Increased risks exist with the added adapter, such as disconnection from the light

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892 source, and the potential change to the electrical safety and electromagnetic compatibility
893 (EMC) of the device.

894

895 *A3.1 Is there a significant change to device performance or safety specifications?*

896 Yes. Disconnection from a light source during a procedure could result in a loss of imaging
897 and adverse events such as increased procedure time or other patient injuries such as
898 perforation. Additionally, testing should also be performed for the electrical safety and EMC
899 of the device.

900

901 **Decision:** Remanufacturing.

902

903 **Example E.10**

904 **Activity:** The motor on a powered wheelchair no longer functions and does not propel the
905 wheelchair as intended. The motor was inspected and it was determined that the motor
906 should be replaced. Neither the identical motor nor one with similar specifications could be
907 located. A motor of similar size was inserted with different power and speed specifications.

908

909 **Relevant questions:**

910 *A1. Add, remove, or change a component/part/material that directly or indirectly contacts*
911 *body tissue?*

912 No. The motor does not directly or indirectly contact body tissue.

913

914 *A2. Add or remove component/part/material or change the dimensional or performance*
915 *specifications of a component/part/material?*

916 Yes. The original motor was removed and replaced.

917

918 *A2.1 Is there a significant change to device performance or safety specifications?*

919 Yes. While the motor has the same physical dimensions, the replacement motor has a
920 different power output and maximum speed than the legally marketed device. This
921 significantly changes the device's performance specifications because the wheelchair can go
922 faster than intended. This also significantly changes the device's safety specifications
923 because the controller and software to operate the wheelchair may no longer be compatible
924 with the motor.

925

926 **Decision:** Remanufacturing.

927

928 **Example E.11**

929 a. **Activity:** The liquid cooling system responsible for maintaining the temperature of a
930 transcranial magnetic stimulation (TMS) coil is malfunctioning and causing the system to
931 overheat. The cooling system was inspected and it was determined that the pump
932 circulating the liquid coolant stopped functioning. A replacement pump was located and
933 installed with no additional changes to the device.

934

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935 **Relevant questions:**

936 *A1. Add, remove, or change a component/part/material that directly or indirectly*
937 *contacts body tissue?*

938 No. The liquid coolant is maintained in the sealed coolant system and neither the liquid
939 coolant nor the pump directly or indirectly contacts body tissue.

940
941 *A2. Add or remove component/part/material or change the dimensional or performance*
942 *specifications of a component/part/material?*

943 Yes, the pump was replaced.

944
945 *A2.1 Is there a significant change to device performance or safety specifications?*

946 No. Both the dimensions and performance specifications of the original pump were
947 assessed in comparison to the replacement part. The replacement pump has the same
948 dimensional and performance specifications of the original pump. The overall
949 performance and safety specifications of the TMS coils were verified by testing to be the
950 same.

951
952 *A3. Is there a new or modified risk or is there a change in the performance or safety*
953 *specifications?*

954 No. A risk-based assessment identified no new or modified risks because the replacement
955 pump is equivalent to that used in the OEM's legally marketed device and there is no
956 change in the device performance or safety specifications.

957
958 **Decision:** Not Remanufacturing.

959
960 b. **Activity:** The liquid cooling system responsible for maintaining the temperature of a
961 TMS coil is malfunctioning and causing the system to overheat. The cooling system was
962 inspected and it was determined that the pump circulating the liquid coolant stopped
963 functioning. A replacement pump was located with the same size and flow specifications,
964 but it uses a different coolant liquid. The pump was replaced with one that uses a
965 different coolant into the cooling system.

966
967 **Relevant questions:**

968 *In this example, the answer to flowchart question A1 is the same as Example E.11.a.*

969
970 *A2. Add or remove component/part/material or change the dimensional or performance*
971 *specifications of a component/part/material?*

972 Yes. A replacement pump that uses a different coolant liquid was installed.

973
974 *A2.1 Is there a significant change to device performance or safety specifications?*

975 Yes. Although the pump has the same dimensional and flow specifications as the original
976 pump, the new pump uses a different liquid coolant. The new liquid coolant does not
977 have the same heat capacity as that used in the legally marketed device. Verification and
978 validation testing was performed and it was determined that there was a significant

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979 change to cooling effectiveness, which poses a safety hazard when the TMS coil is not
980 properly cooled. This may burn the patient or cause further device malfunctions.

981

982 **Decision:** Remanufacturing.

983

984 **Example E.12**

985 **Activity:** An energy-delivering aesthetic device has multiple compatible handpieces with
986 specific areas of application. Applicator A can only be used for the chin, while Applicator B
987 can only be used on the abdomen. An entity cannibalizes Applicator B and uses those parts to
988 repair Applicator A for use on the chin.

989 **Relevant questions:**

990 *A1. Add, remove, or change a component/part/material that directly or indirectly contacts*
991 *body tissue?*

992 Yes. The distal end of Applicator B is used to reconstruct Applicator A. It directly contacts
993 the patient and delivers the energy.

994

995 *A1.1 Is there a significant change to device performance or safety specifications?*

996 No. The distal end of both applicators has identical materials and the reprocessing
997 instructions provided by the OEM are the same for both applicators. A risk-based assessment
998 was performed to determine the effects of implementing these repairs on the biocompatibility
999 and reprocessing. A biocompatibility assessment and reprocessing risk assessment were used
1000 to determine that the performance and safety specifications of the device were not
1001 significantly changed.

1002

1003 *A2. Add or remove component/part/material or change the dimensional or performance*
1004 *specifications of a component/part/material?*

1005 Yes. The distal end of Applicator B has different dimensional specifications compared to
1006 Applicator A.

1007

1008 *A2.1. Is there a significant change to device performance or safety specifications?*

1009 Yes. The surface area that contacts the patient has increased by 150%. The increase in
1010 surface area changes the energy output delivered to the patient, which significantly changes
1011 both the performance and safety specifications of Applicator A.

1012

1013 **Decision:** Remanufacturing.

1014

1015 (2) Software activities

1016 **Example S.1**

1017 **Activity:** A specular microscope with a camera is intended for examination of corneal
1018 endothelium and for measurement of the thickness of the cornea. The software was updated
1019 to implement an OEM-authorized patch.

1020

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1021 **Relevant analysis:** The installation of this OEM-authorized patch does not significantly
1022 change the device performance or safety specifications. See Section VII of this draft
1023 guidance for further discussion of changes involving software. The patch is intended to
1024 maintain the original specifications.
1025

1026 **Decision:** Not Remanufacturing.
1027

Example S.2

1029 **Activity:** A device has the capability of real-time remote customer service where the current
1030 status of the device can be accessed. A capability is added so that the customer service
1031 technician can access and directly manipulate the device, including changing device settings,
1032 resetting the device, delivering energy, and positioning the device.
1033

1034 **Relevant analysis:** The capability of the customer service technician to control the device
1035 introduces new risks (e.g., accidental device reset, unintended device movement) and
1036 functionality (remote control and access) that significantly changes the finished device's
1037 performance and safety specifications.
1038

1039 **Decision:** Remanufacturing.
1040

Example S.3

1042 **Activity:** A device that connects to a facility's network has software that was designed to run
1043 the Microsoft Windows operating system (OS). Adjustments are made to allow the device to
1044 run using a Linux OS.
1045

1046 **Relevant analysis:** This change introduces new risks and may impact mitigations for existing
1047 risks that significantly change the finished device's performance and safety specifications.
1048 This is a redesign of the product and includes the addition of integration with both device
1049 drivers for the target OS as well as specific features of the OS.
1050

1051 **Decision:** Remanufacturing.

1052 **Appendix B. Documentation examples**

1053 The examples below are to illustrate one possible approach to documentation; other approaches
1054 may also be appropriate. Entities are encouraged to use an approach that works for their specific
1055 purposes, taking into account the considerations discussed above. The first example
1056 demonstrates a simple change that does not necessitate detailed analysis. The second example
1057 demonstrates a more complex change for which additional analysis and reference to supporting
1058 documentation are warranted. These are generalized examples to demonstrate documentation
1059 principles and do not necessarily account for every possible detail, risk, or consideration.
1060

1061 **Remanufacturing Assessment**
1062 **(Example 1)**

1063
1064 **Product:** Pump ABC, Serial# 123-456

1065
1066 **Date of activities performed:** 12/11/2018

1067
1068 **Date assessment performed:** 12/10/2018

1069
1070 **Description of device:** Syringe pump

1071
1072 **Description of activities performed:** Replaced broken door with part #xxx

1073
1074 **Determination of whether the activity is remanufacturing:** While a change to a body
1075 contacting component, the door used was OEM-provided and is identical to the broken door.
1076 Because it is a replacement of an identical part, there are no changes to performance or safety
1077 specifications. This activity is not remanufacturing.

1078
1079 **Reference to related documents supporting the decision-making process:** N/A

1080
1081 **Technician performing service:** xxx

1082
1083 **Reviewed by:** xxx

1084
1085 **Signature(s):** xxx

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1086 **Remanufacturing Assessment**
1087 **(Example 2)**

1088
1089 **Product:** Endoscope Infinity, Serial #4FR992

1090
1091 **Date of activities performed:** 9/24/2018-9/30/2018

1092
1093 **Date assessment performed:** 9/22/2018

1094
1095 **Description of device:** Flexible endoscope

1096
1097 **Description of activities performed:** Repair device; lens, irrigation channel, and shaft exterior
1098 replaced. Each change was individually and cumulatively assessed.

1099
1100 **Determination of whether the activity is remanufacturing:**

1101 *Lens Assessment*

- 1102 • Original lens is cracked and needs replacement; OEM lens and epoxy not available for
1103 purchase;
- 1104 • Equivalent lens with same performance specifications and dimensions used (see
1105 biocompatibility assessment (BCA) #EI-001 and Component Comparative Analysis
1106 Report (CCAR) #EI-002);
- 1107 • Epoxy used to secure lens is equivalent to OEM epoxy (see BCA #EI-003 and CCAR
1108 #EI-004); and
- 1109 • Leak, optics, and field of view were verified to be within OEM specifications.

1110
1111 *Irrigation Channel Assessment*

- 1112 • Irrigation channel is worn and leaking fluid into the device;
- 1113 • OEM part available for purchase and used (part #XX44); and
- 1114 • Irrigation channel installed and checked for leaks and functionality.

1115
1116 *Shaft Exterior Assessment*

- 1117 • Shaft exterior damaged during repair activities and needs replacement;
- 1118 • OEM part not available for purchase; and
- 1119 • Equivalent shaft exterior with same performance specifications and dimensions used (see
1120 BCA #EI-005 and CCAR #EI-006).

1121
1122 *Cumulative Change Assessment*

- 1123 • Full device specification list inspected and passed (see Customer Evaluation Report
1124 #88239 and OEM specification sheet);
- 1125 • No change in component exposure to reprocessing when following OEM reprocessing
1126 instructions;
- 1127 • A risk-based assessment was performed in each CCAR report; modified risks were
1128 identified with using non-OEM parts but were demonstrated as not significantly changing
1129 the device's performance or safety specifications, or intended use; and

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- 1130 • No other change in the risks, or change in the performance or safety specifications, have
1131 been identified for the cumulative changes made.

1132

1133 This activity is not remanufacturing.

1134

1135 **Reference to related documents supporting the decision-making process:**

1136 1. BCA #EI-001

1137 2. CCAR #EI-002

1138 3. BCA #EI-003

1139 4. CCAR #EI-004

1140 5. BCA #EI-005

1141 6. CCAR #EI-006

1142 7. Customer Evaluation Report #88239

1143 8. Endoscope Infinity Specification Sheet

1144

1145 **Technician performing service:** xxx

1146

1147 **Reviewed by:** xxx

1148

1149 **Signature(s):** xxx

DRAFT