**Predicates and Substantial Equivalence**

1 Predicate and Reference Devices

*【For aid in finding appropriate predicate devices, please consult the webpage How To Find A Predicate Device.*

*Resources*

*How To Find A Predicate Device*

*<https://www.fda.gov/medical-devices/premarket-notification-510k/how-find-and-effectively-use-predicate-devices>】*

1.1 Primary Predicate

1.1.1 Is this a Preamendments or Exempt device without a submission number?

*【The term “preamendments device” refers to devices legally marketed in the U.S. by a firm before May 28, 1976 and which have not been significantly changed or modified since then, and for which an order requiring a premarket approval (PMA) application has not been significantly changed or modified since then, and for which an order requiring a premarket approval (PMA) application has not been published by FDA. If a Preamendment device is claimed as a predicate device, be sure to see the Preamendment Status webpage for the documentation that should be provided.*

*Preamendment documentation should be attached alongside the Substantial Equivalence Comparison documentation at the end of this section.*

*Resources:*

*Preamendment Status webpage:*

*<https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status>*

*】*

1.1.2 Predicate Submission Number (e.g., K210001)

*【If the predicate device is a 510(k), De Novo or down-classified PMA, please provide the submission number (e.g., K#, DEN# or P#).】*

1.1.3 Predicate Device Trade Name

1.1.4 Predicate Device Primary Product Code

1.2 Substantial Equivalence Comparison

1.2.1 If the device has different indications for use in comparison to the predicate device(s), describe why the differences do not constitute a new intended use. If the indications for use are the same, state this in the text box below.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), and the Indications are different in comparison to your predicate device(s), you must include the information from 21 CFR 807.92(a)(5) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE RATIONALE TEXTBOX BELOW.

CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

*【In accordance with 21 CFR 807.92(a)(5), please ensure any rationale includes an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not constitute a new intended use of the device when used as labeled.*

*Resources:*

*21 CFR 807.92(a)(5)*

*<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=807.92>*

*】*

1.2.2 If the device has the same technological characteristics (i.e., design, material, chemical composition, principle of operation, energy source, etc.) as the predicate device(s) identified above, include a summary in the memo box below of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), include a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified above.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include the information from 21 CFR 807.92(a)(6) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DESCRIPTION TEXTBOX BELOW.

CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

*【See 21 CFR 807.92(a)(6) for the regulatory requirements regarding this question.*

*Resources*

*21 CFR 807.92(a)(6)*

*<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=807.92>*

*】*

1.2.3 Please attach your Substantial Equivalence Comparison in tabular format. Please ensure the table(s) includes a comparison of the Indications for Use as well as a comparison of the pertinent technology characteristics of your device and your predicate device(s).

If your submission is intended for the safety and performance pathway, then you should satisfy the Substantial Equivalence comparison as outlined in the relevant guidance. Please open the link in the help text for more information.

*【In the Substantial Equivalence Comparison, please include an analysis of why any differences the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate).*

*For new or modified Indications for Use: In rare instances, FDA may rely upon clinical data to determine that new or modified indications for use all within the same intended use as a predicate device.*

*In addition, please include an analysis of why any differences between the subject device and predicate(s) do not affect safety or effectiveness, or raise different types of questions of safety and effectiveness (see section 513(i)(1)(A) of the FDC Act and 21 CFR 807.87(f)).*

*Resources*

*21 CFR 807.87(f)*

*<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=807.87>*

*Safety and Performance Based Pathway*

*<https://www.fda.gov/medical-devices/premarket-notification-510k/safety-and-performance-based-pathway>*

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