**Classification**

5.1 Add a primary product code and any associated product codes below. You may type in the primary product code directly (only the product code field is required) or you may filter down by choosing first a medical specialty, regulation, then product code. If a device specific guidance is available for the product code, the guidance name and web link will be displayed. Use the Product Classification Website resource in the help text to obtain information about your product code and check the regulation text for any special controls that need to be considered (e.g, PAE and 21 CFR 890.3450).

*【This question intends to obtain the proper classification you believe your device should be cleared or approved under. This information is necessary for several reasons:*

* *It will let you known FDA’s best judgement about which, if any, marketing submission is required for your product (e.g., 510(k), PMA, De Novo);*
* *It will let you know whether any guidance is available for your device to help ensure you are providing all of the necessary information in your submission;*
* *It allows FDA to route your submission to the appropriate review Division;*
* *It can help you compare your device to similar devices.*

*Your device will not be actually classified until it is cleared in a 510(k) or granted in a De Novo. If you find that your device falls under a regulation that is exempt from 510(k) review, you should be sure that the technology and indications for your device are consistent with the regulations or a device found substantially equivalent under that regulation. You may need to submit a 510(k) if you trip the limitations of exemption identified in the applicable .9 regulation (e.g., 872.9).*

*The Medical Specialty (usually equivalent to Review Panel) is a very general description of a particular medical area, and is the highest level of classification. All classified devices will reside under one of these classifications. Each Medical Specialty includes several Regulations, and within each Regulation resides one or more Product Codes (a.k.a. pro code).*

*The Medical Specialty is identified by a two letter code, for example PM, and is associated with the first 3 numerals in the regulation number, for this example 890. The regulation number is a 7 digit numeral, for example 890.5850 (formally the regulation is 21 CFR 890.5850 since all medical device regulations reside in Title 21 of the Code of Federal Regulations).*

*The Product Code will identify your device type, and is identified by a 3 three letter code, for example IPF. A device should always have a primary product code, but may have additional product codes associated that may or may not fall within the primary Regulation or Medical Specialty. Regulatory classes for devices are Class I, II, or III, with III being highest risk.*

*If multiple product codes apply to your submission (e.g., bundled submission, multiple device functions), then choose the product code with the highest regulatory class as your primary product code. If all relevant product codes share the same regulatory class, choose the product code with the highest safety risk as the primary product code.*

*This information is vital in understanding the kinds of specific information and data the FDA will be requesting in regards to your device. If you enter a product code at the 510(k) Search Website, it will inform you of the 510(k)s previously cleared under that product code, and which are appropriate predicate devices for use in your submission for your product code.*

*If you are unable to determine the regulation that best describes your device, FDA can perform this function for you (for a fee) with the submission of a Request for Classification 513(g) to our Document Control Center. A 513(g) is FDA’s best judgment about how the product would be regulated. A 513(g) response is not a classification decision for a device and does not constitute FDA clearance or approval for commercial distribution.*

*Resources:*

*Guidance: “*

*FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act”*

*Classify Your Medical Device Website*

*<https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device>*

*】*

5.2 Medical Specialty

5.3 Regulation

5.4 Product Code

5.5 Associated Product Code(s)

*【Add any product codes for features of the device or system that are not covered by the primary product code. For example, if the device includes accessories or components covered under other product codes, list those product codes here.】*