**Device Description**

**1 Listing of Device(s)**

*【A model/variant/configuration of a device has common specifications, performance and composition, within limits set by the applicant.*

*If the submission contains multiple devices as part of a kit, please provide only the name of the kit here. You will have the opportunity to identify all system/kit components or accessories later in this section.*

*Note that, for De Novo requests, only one device type will be reviewed; therefore, generally, we will not accept bundled De Novos.】*

**2 General Device Characteristics**

2.1 Is the device life-supporting or life-sustaining?

*【Life-supporting or life-sustaining device means a device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life. (21 CFR 860.3(e))】*

2.2 Are there any direct or indirect tissue contacting components?

*【Direct Contact:*

*Defined as a device or device component that comes into physical contact with body tissue. Examples of devices that have Direct Contact include: implanted cardiovascular stents, implanted replacement hips, blood pressure cuffs, and skin electrodes.*

*Indirect Contact:*

*Defined as a device or device component through which a fluid or gas passes, prior to the fluid or gas coming into physical contact with body tissue (in this case the device or device component itself does not physically contact body tissue).*

*Examples of devices that have Indirect Contact include: infusion pumps and ventilators.*

*Typically devices that indirectly contact the body have direct contacting components, such as solution administration sets, extension sets, transfer sets, and blood administration sets, where a needle would have direct contact with the blood, and all other components of the set would indirectly contact the body via contact with fluid that is allowed to enter into the blood stream through the needle. Catheters with infusion lumens are another device where some components have direct contact with blood and cardiovascular tissue (e.g., balloon, outer catheter shaft), while other components have only indirect contact (e.g., infusion ports or lumens down the internal length of the catheter).】*

2.3 Does the device use software/firmware?

*【For more information, refer to the guidance document entitled “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”】*

2.3.1 Is the device, or does it contain, digital health technology?

*【Digital Health Technology includes the following items:*

*Mobile Apps including Mobile Medical Apps;*

*Machine Learning;*

*Advanced Analytics;*

*Cloud Technology;*

*Wireless Communication;*

*Interoperability with other devices or systems;*

*Software as a Medical Device; and*

*Cybersecurity.】*

2.3.2 Please check the attributes that are applicable to your device.

*【Indicate if a network is used, regardless of whether it is active or not. Example of wireless communication include but are not limited to wifi, bluetooth, NFC, bluetooth energy (BLE), and inductive communication. If the device includes a USB, serial port, JTAG, or removable media, whether or not it is used by the device, indicate that it is used. If the device/system does not include any of these connections, no Cybersecurity data need to be provided.】*

2.4 Is the device or a component packaged as sterile?

2.5 The device/system uses or is... (choose all that apply)

*【If the device is or uses a Single Use Device (SUD), ensure the single use device/component is labeled “Do Not Reuse,” “Single Use,” or “Single Use Only.”*

*If the device/system only uses or is a Single Use Device (SUD) that is non-sterile or is packaged as sterile (i.e., this is the only option checked), no Reprocessing review is needed.*

*If the device or a component is reusable, cleaning/disinfection instructions should be included in the labeling, unless a valid justification is provided in the Reprocessing section for not including them (e.g., the device is an in vitro diagnostic device for laboratory use, or the device is a software only device (SaMD)). Be sure the device is labeled for either single or multiple patient use (or both if applicable).】*

2.6 The environment of use of the device/system includes...

(choose all that apply)

*【A professional healthcare facility is either:*

1. *Any environment where personnel with medical training are continually available to oversee or administer the use of medical devices. This includes, but is not limited to, hospitals, long-term care facilities, nursing homes, emergency medical services, clinics, physicians’ offices, and outpatient treatment facilities; or*
2. *A clinical laboratory.*

*A home use device is a medical device labeled for use in any environment outside a professional healthcare facility. This includes but is not limited to outdoor environments, office environments, schools, vehicles, emergency shelters, and independent living retirement homes. If the device is intended for use in professional healthcare facilities and also outside those facilities, it meets this definition.*

*If applicable, ensure the labeling incorporates the principles of the “Home Use guidance document.”*

*In addition, ensure adequate performance data are provided to support home use.*

*Resources:*

*Guidance: “Design Considerations for Devices Intended for Home Use”】*

2.7 Is the device a combination product or does a Request For Designation (RFD) / pre-RFD exist for the product?

*【Combination products are defined in 21CFR3.2(e). The term combination product includes:*

1. *A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;】*
2. *Two or more separate products packaged together in a single package or as a unit and comprise of drug and device products, device and biological products, or biological and drug products;*
3. *A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or sign*
4. *Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.*

*Information regarding the drug/biologic constituent part of a combination product may be needed and accounted for throughout the various sections of your premarket submission. In addition, as described in Product Stability documentation, medicinal substance refers to the drug/biologic constituent part of combination product as defined in 21 CFR 3.2(e).*

*A company may submit a Request for Designation (RFD) to obtain a formal agency determination of a combination product’s primary mode of action as well as assignment of the lead agency center for the product’s premarket review and regulation.*

*Resources*

*21CFR 3.2(e)*

*<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=3.2>*

*Combination Products Website*

*<https://www.fda.gov/combination-products>*

*RFD/Pre-RFD Process*

*<https://www.fda.gov/combination-products/rfd-process>*

*】*

2.8 Is the device electrical (battery or wall powered)?

*【A device is considered Mains powered if it receives power from a wall socket. A device is considered Battery powered if it uses any battery in its operation (excluding wrist watch type batteries attached to circuit boards).*

*If the device is battery powered, and is charged from Mains (regardless of whether the device is operable or not while charging), choose battery and mains powered.】*

2.8.1 Does the device/system include wireless technology?

*【More information about wireless technology can be found in the guidance document entitled “Radio Frequency Wireless Technology in Medical Devices.”*

*Resources:*

*Guidance: “Radio Frequency Wireless Technology in Medical Devices”】*

2.9 Please check the attributes that are applicable to your device. If none apply, keep all unchecked.

*【Medical Counter Measures (MCM):*

*Medical countermeasures are defined as medical products which counter Chemical, Biological, Radiological or Nuclear (CBRN) threats and Emerging Infectious Diseases. Examples include both pharmaceutical interventions, such as vaccines, antimicrobials, antidotes, antitoxins, and medical devices such as ventilators, diagnostics, personal protective equipment and patient decontamination that may prevent, mitigate, or treat the adverse health effects of any CBRN threat.*

*Nanotechnology:*

*Check the checkbox if the device contains materials in the nanoscale range (i.e., with at least one dimension in the size range of approximately 1 nanometer(nm) to 100nm).*

*Please consult the “Nanotechnology guidance document” for more information.*

*Reprocessed Single Use Device:*

*Reprocessed Single Use Devices are those for which an original equipment manufacturer (OEM) has FDA-clearance for a single use, and are now being proposed for reprocessing and additional use (typically by a third party). A De Novo submission should not be a Reprocessed SUD. If the device is a Reprocessed Single Use Device, consult the “Reprocessed SUD guidance document” as well as the FAQ and FR Notice.*

*Animal-Derived Material(s):*

*For further information regarding devices with animal-derived materials you can consult the guidance document “Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices).”*

*Predetermined Change Control Plan (PCCP):*

*This describes planned that may be made to the device (and that would otherwise require a new premarket submission). (see 515C of the FDC Act)*

*Resources*

*Guidance: “Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology”*

*Guidance: “Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed SingleUse Medical Device”*

*Guidance: “Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices)”】*

**3 Description**

3.1 Please provide a Device Description Summary below, and ensure it includes an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties.

*【We recommend you include a brief description of the principle of operation for achieving the intended effect. We also recommend that you include a brief description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.*

*If you have links to online videos or resources that would aid in the review of your device, please add them to your summary.】*

3.2 Comprehensive Device Description and Principles of Operation Documentation

*【Please attach documentation that describes your device in detail. This should include key design features for the principle of operation and how performance is achieved.*

*Please ensure you include a detailed description of any components or accessories for use with your device, and specify the name of the original equipment manufacturer (if the components or accessories are third-party produced). If your device is adjunctive to another legally marketed device, please ensure your device description clearly defines the interfaces that exist and dependencies.】*

3.3 Device Pictures, Illustrations, Schematics, and/or Diagrams. Attach a justification if the device does not have a physical form.

3.4 Description of Device Packaging

*【This includes information regarding the packaging of the devices, including, when applicable, primary packaging, secondary and any other packaging associated.*

*Specific packaging of accessories marketed together with the medical devices shall also be described.】*

**4 System/Kit Components and Accessories**

4.1 Is the device intended to be marketed with multiple system/kit components or accessories?

*【For the purposes of this eSTAR, system components are those individual parts or assemblies intended to be used together to fulfill some or all of the device’s intended functions. Kit components are often those assembled together strictly for the “convenience” of the purchaser.*

*An accessory is a finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices.*

*Resources:  
Guidance: “Medical Device Accessories – Describing Accessories and Classification Pathways”】*

4.1.1 Under section 513(f)(6), are you requesting risk-based classification of an accessory that is not explicitly identified in a classification regulation, or has not been included in a cleared 510(k), approved PMA, or granted De Novo request?

*【Section 513(f)(6)(C) of the FD&C Act authorizes a person submitting a 510(k), PMA, or PMA supplement to request proper classification of an accessory that has not been previous classified. This classification “shall....be based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used”(section 513(f)(6)(A) of the FD&C Act).】*

4.1.2 If the device is intended to be marketed as a kit, for the purposes of this premarket notification [510(k)], please attach your signed kit certification statement and please identify all the kit components included in your kit certification. For more information, including the text of the kit certification statement, see FDA's guidances, "Kit Certifications for 510(k)s" and "Convenience Kits Interim Regulatory Guidance." If you cannot make the kit certification statement for each component of your kit, you must provide a list of these excluded components in the requested attachment below.

4.1.3 Please attach a list of all the system/kit components and accessories that are part of this submission. Please also include the submission number if the system/kit component or accessory received marketing authorization. For 510(k)s, only include kit components here that are not part of the kit certification statement if this certification was provided (see help text). If you only have kit components that are part of the kit certification statement, please provide an attachment here that states this.

*【For 510(k) only, if you cannot make the kit certification standards for each component of your kit, you must itemize the components without a pre-Amendments exemption, or premarket notification notification status. If you cannot make the referenced statement in the second paragraph of the kit certification statement for each component of your kit, you must itemize these components, state whether they are pre-Amendments, exempt, or have been found substantially equivalent through the premarket notification process, and describe how you further process them (e.g., sterilize, package/repackage, label/relabel, etc.).】*

4.1.4 Please attach System/Kit Component and/or Accessory Pictures, Illustrations, Schematics, and/or Diagrams

**5 Guidance and Special Controls Adherence**