Submission Date: Month DD, 202x

Food and Drug Administration

Center for Devices and Radiological Health

Document Mail Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, Maryland 20993-0002

United States of America

## Administrative Information

FDA Submission Document No: K123456 / S001

Type of 510(k) Submission: 510(k) Submission

Address: [Client’s Address]

Company Contact Person: [Client’s Name]

Phone: +1.xxx.xxx.xxxx

Email: [client email]

Establishment Registration: N/A – company is not currently distributing in the USA

Submission Contact Person: [Consultant’s Name]

Phone: +1.xxx.xxx.xxxx

Email: [rob@fdaestar.com](mailto:rob@fdaestar.com)

Device Common Name: [Common Name]

Device trade/proprietary name: [Trade Name] – Model 1

[Trade Name] – Model 2

Continued Confidentiality: Request made for continued confidentiality.

Classification Name: [Classification Name]

Classification Regulation: 21 CFR 8xx.xxxx

Device Classification: Class 2 (or unclassified)

Device Panel: [Review Panel or Medical Specialty]

Device Product Code: [ABC]

Prior FDA Document Numbers: No prior correspondence regarding this submission.

OR

No previous correspondence regarding this submission. However, the following submissions are related to this device.

OR

List each of the document numbers applicable to this submission (e.g., K123456 and Q191234 and Q191234/S001)

## Reason for the 510(k) Submission:

This is a new device submission for a pre-market notification 510(k).

## eSTAR Statement:

This electronic signed cover letter is enclosed with an eSTAR PDF as an embedded attachment. We are submitting this eSTAR PDF via the FDA Customer Collaboration Portal (CCP).

**Design and Use of the Device:**

|  |  |  |
| --- | --- | --- |
| Question | YES | NO |
| Is the device intended for prescription use (21 CFR 801 Subpart D)? |  | ✓ |
| Is the device intended for over-the-counter use (21 CFR 807 Subpart C)? | ✓ |  |
| Does the device contain components derived from a tissue or other biologic source? |  | ✓ |
| Is the device provided sterile? |  | ✓ |
| Is the device intended for single use? | ✓ |  |
| Is the device a reprocessed single use device? |  | ✓ |
| If yes, does this device type require reprocessed validation data? | N/A | N/A |
| Does the device contain a drug? |  | ✓ |
| Does the device contain a biologic? |  | ✓ |
| Does the device use software? | ✓ |  |
| Does the submission include clinical information? |  | ✓ |
| Is the device implanted? |  | ✓ |

I look forward to the results of your review for this notification. Please contact me if you have any questions or further information is needed.

[Alternate wording] I look forward to the results of your review for this notification. Please contact Rob Packard at +1.802.258.1881 or [rob@fdaestar.com](mailto:rob@fdaestar.com) if you have any questions or further information is needed.

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[Your Name], [Title]

[Company Name]