SHINHUNG MST CO., LTD.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave.
Suite 160
Irvine, California 92612

June 4, 2023

Re: K221752
Trade/Device Name: Stella
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: February 28, 2023
Received: March 6, 2023

Dear Priscilla Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K221752

Device Name
Stella

Indications for Use *(Describe)*
The Stella is intended to be surgically placed in the upper or lower jawbone to provide support for prosthetic devices, such as artificial teeth, restoring the patient's chewing capabilities. The Stella is intended for delayed loading and immediate loading is possible when good primary stability is achieved and with appropriate occlusal loading.
The Stella Abutment is intended to be connected to the dental implant to retain the overdenture or partial denture.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

(K221752)

This summary of 510(K) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 6/02/2023

1. Submitter

SHINHUNG MST CO., LTD.
110-2, Donghwagondan-ro, Munmak-eup,
Wonju-si, Gangwon-do, Republic of Korea, 26365

Tel: +82-33-730-1901

2. U.S Agent/Contact Person

Priscilla Chung
LK Consulting Group USA, Inc.
18881 Von Karman STE 160, Irvine CA 92612
Phone: 714-202-5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

- Trade Name: Stella
- Common Name: Dental Implant System
- Classification Name: Endosseous Dental Implant
- Product Code: DZE, NHA
- Classification regulation: 21CFR 872.3640

4. Predicate Device:

SSII/III SA Fixture by OSSTEM Implant Co., Ltd. (K120847)
Luna Dental Implant System by SHINHUNG MST CO., LTD. (K123155 / K160106)

5. Description:

Stella is a dental implant fixture that is implanted in the jawbone to support and maintain prosthetic restoration teeth or dentures in case of partial or total loss of teeth as a material for dental surgery. The fixture is made of titanium (ASTM F67, Grade 4), and the retention area is surface treated by spraying with Al2O3 (alumina) powder and then

pickling to roughen the surface.
The system incudes Healing Abutment, Simple Abutment, Duo Abutment, Contour Abutment, Angled Abutment, and Temporary Abutment.

6. Indication for use:

The Stella is intended to be surgically placed in the upper or lower jawbone to provide support for prosthetic devices, such as artificial teeth, restoring the patient's chewing capabilities. The Stella is intended for delayed loading and immediate loading is possible when good primary stability is achieved and with appropriate occlusal loading.
The Stella Abutment is intended to be connected to the dental implant to retain the overdenture or partial denture.

7. Basis for Substantial Equivalence

Comparison Chart

- Dental fixture

Device Name	**Subject Device**	**Predicate Device**	
Manufacturer	SHINHUNG MST CO., LTD.	Osstem Implant Co., Ltd.	SHINHUNG MST CO., LTD.
Device Name	Stella	SSII/III SA Fixture	Luna Dental Implant System
Design			
510(k) Number	K221752	K120847	K123155 / K160106
Intended use	The Stella is intended to be surgically placed in the upper or lower jawbone to provide support for prosthetic devices, such as artificial teeth, restoring the patient's chewing capabilities. The Stella is intended for delayed loading and immediate loading is possible when good primary stability is achieved and with appropriate occlusal loading. The Stella Abutment is intended to be connected to the dental implant to retain the overdenture or	ET/SS Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. The abutment is intended for use with a dental implant fixture to provide support for prosthetic restorations such as crowns, bridges, or	The Luna Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

	partial denture.	overdenture.	
Structure	- Tissue level fixture - Self tapping - Internal Octagonal connection - Taper body shape	- Tissue level fixture - Self tapping - Internal Octagonal connection - Straight / Taper body shape	- Bone level fixture - Self tapping - Internal Hexagonal connection - Taper body shape
Platform Diameter (D) (mm)	4.8, 6.0	4.8, 6.0	3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 7.0
Body Diameter (D) (mm)	3.7, 4.2, 4.7, 5.2	3.5, 4.0, 4.5, 5.0, 6.0, 7.0	3.7, 4.2, 4.7, 5.2, 5.7, 6.0, 7.0
Length (mm)	7.0, 8.5, 10.0, 11.5, 13.0, 15.0 *The following size configurations are not included. · 4.8mm platform diameter x 3.7mm body diameter x 7.0mm length. · 4.8mm platform diameter x 5.2mm body diameter x all length. · 6.0mm platform diameter x 3.7 mm body diameter x all length. · 6.0mm platform diameter x 4.2 mm body diameter x all length.	6.0, 7.0, 8.5, 10.0, 11.5, 13.0 *The following size configurations are not included. · 4.8mm platform diameter x 3.5mm body diameter x 7.0mm length. · 4.8mm platform diameter x all body diameter x 6.0mm length. · 4.8mm platform diameter x 5.0mm body diameter x all length. · 4.8mm platform diameter x 6.0mm body diameter x all length. · 4.8mm platform diameter x 7.0mm body diameter x all length. · 6.0mm platform diameter x 3.5mm body diameter x all length. · 6.0mm platform diameter x 4.0mm body diameter x all length. · 6.0mm platform diameter x 4.5mm body diameter x 6.0mm length.	7.0, 8.5, 10.0, 11.5, 13.0, 15.0 *The following size configurations are not included. · 3.7mm body diameter x 7.0mm length. · 5.7mm body diameter x 15.0mm length. · 6.0mm body diameter x 15.0mm length. · 7.0mm body diameter x 15.0mm length.
Material	Pure Titanium Gr 4 (ASTM F67)	Pure Titanium Gr 4 (ASTM F67)	Pure Titanium Gr 4 (ASTM F67)
Surface	S.L.A.	S.L.A.	S.L.A.
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile

S.E.	This product has the same intended use as the predicate device, and its main purpose is to restore the masticatory function by implanting it in the toothless areas of the upper and lower jaws. It is a non-submerged fixture identical to Osstem's SSII/III SA Fixture (K120847), and there is a groove for self-tapping at the end of the body. The diameter of the platform is the same as that of the Osstem. The diameter of the body is similar to that of the Osstem, and the safety of the 3.7mm diameter has been proven in the Luna Dental Implant System. In addition, it was confirmed that there was no strength problem through the fatigue test on the fixture diameter 3.7mm. The length of the product is within the range of the length of the Osstem product. The connection to the abutment is also made of an internal octagonal structure. The raw material was made of Pure Titanium Grade 4 (ASTM F67) in the same way as the predicate device, and the surface treatment was SA-treated. It is manufactured through the same raw materials and manufacturing process as our previously licensed Luna Dental Implant Systems (K123155 / K160106). Sterilization is also provided through gamma sterilization.

- Abutment

Device Name	**Subject Device**	**Predicate Device**	
Manufacturer	SHINHUNG MST CO., LTD.	Osstem Implant Co., Ltd.	SHINHUNG MST CO., LTD.
Device Name	Healing Abutment	Healing Abutment	Healing Abutment
Design			
510(k) Number	K221752	K120847	K123155
Diameter (mm)	4.8, 6.0	4.8, 6.0	4.0, 4.5, 5.0, 6.0
Gingiva Height (mm)	2.0, 3.0, 4.0	2.0, 3.0, 4.0, 5.0 *The following size configurations are not included. · 6.0mm diameter x 2.0mm Gingiva height.	2.0, 3.0, 4.0, 5.0, 6.0 *The following size configurations are not included. · 6.0mm diameter x 6.0mm Gingiva height.
Material	Pure Titanium Gr 4	Titanium Alloy Ti-6Al-4V	Pure Titanium Gr 4

	(ASTM F67)	(ASTM F136)	(ASTM F67)
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile
S.E.	Healing Abutment is a product that is used temporarily before installing a permanent superstructure. This product has the same purpose as the predicate device and has a size within the product size range of Osstem. Unlike Osstem's, the raw material was manufactured with Pure Titanium Grade 4 (ASTM F67), and was manufactured with the same material as our previously approved product, Luna Dental Implant System (K123155). It is gamma-sterilized and provided to the user.		

Device Name	**Subject Device**	**Predicate Device**	
Manufacturer	SHINHUNG MST CO., LTD.	Osstem Implant Co., Ltd.	SHINHUNG MST CO., LTD.
Device Name	Simple Abutment	Solid Abutment	Simple Abutment
Design			
510(k) Number	K221752	K120847	K123155
Diameter (mm)	4.8, 6.0	4.8, 6.0	4.1, 4.6, 5.1, 6.1
Post Height (mm)	4.0, 5.5, 7.0	4.0, 5.5, 7.0	4.0, 5.5, 7.0
Material	Titanium Alloy Ti-6Al-4V (ASTM F136)	Titanium Alloy Ti-6Al-4V (ASTM F136)	Titanium Alloy Ti-6Al-4V (ASTM F136)
Sterilization	User sterile	User sterile	User sterile
S.E.	Simple abutments can be used in both anterior and posterior areas of the mouth for cement retained crown and bridge restorations. This product has the same purpose as the predicate device and has a size within the product size range of Osstem. The raw material is the same as the predicate device. In addition, it is manufactured through the same manufacturing process as our Luna Dental Implant System. Our previously approved product, Luna Dental Implant System (k123155), uses the same raw materials as the applied product, but only a part of it is coated with TiN. However, the whole is not coated with TiN, and it can be seen that the portion with TiN coating is the worst case in terms of biocompatibility. Thus, the safety of the raw material is demonstrated. This product is sterilized by the user by the method described in the user manual.		

Device Name	**Subject Device**	**Predicate Device**	
Manufacturer	SHINHUNG MST CO., LTD.	Osstem Implant Co., Ltd.	SHINHUNG MST CO., LTD.
Device Name	Duo Abutment	ComOcta Abutment	Duo Abutment

Design			
510(k) Number	K221752	K120847	K123155
Diameter (mm)	4.8, 6.0	4.8, 6.0	4.6, 5.1, 6.1
Post Height (mm)	4.0, 5.5, 7.0	4.0, 5.5, 7.0	4.0, 5.5, 7.0
Material	Pure Titanium Gr 4 (ASTM F67)	Titanium Alloy Ti-6Al-4V (ASTM F136)	Pure Titanium Gr 4 (ASTM F67)
Sterilization	User sterile	User sterile	User sterile
S.E.	Duo abutment can be used in both anterior and posterior areas of the mouth for cement retained crown and bridge restorations. This product has the same purpose as the predicate device and has a size within the product size range of Osstem. The raw material is the same as the predicate device. In addition, it is manufactured through the same manufacturing process as our Luna Dental Implant System. Our previously approved product, Luna Dental Implant System (k123155), uses the same raw materials as the applied product, but only a part of it is coated with TiN. However, the whole is not coated with TiN, and it can be seen that the portion with TiN coating is the worst case in terms of biocompatibility. Thus, the safety of the raw material is demonstrated. This product is sterilized by the user by the method described in the user manual.		

Device Name	**Subject Device**	**Predicate Device**	
Manufacturer	SHINHUNG MST CO., LTD.	Osstem Implant Co., Ltd.	SHINHUNG MST CO., LTD.
Device Name	Contour Abutment	ComOcta Milling Abutment	Contour Abutment
Design			
510(k) Number	K221752	K120847	K123155
Diameter (mm)	5.5, 6.7	4.8, 6.0	4.1, 5.6
Gingiva Height (mm)	2.0, 4.0	2.0	1.5, 3.0
Material	Pure Titanium Gr 4 (ASTM F67)	Titanium Alloy Ti-6Al-4V (ASTM F136)	Pure Titanium Gr 4 (ASTM F67)
Sterilization	User sterile	User sterile	User sterile
S.E.	This product has the same purpose as the predicate device and has a size within the product size range of Osstem. The raw material is the same as the predicate device (K123155). In addition, it is manufactured through the same manufacturing process as our Luna Dental Implant System. Our previously approved product, Luna Dental Implant System (k123155), uses the same raw materials as the applied product, but only a part of it is coated with TiN. However, the whole is not coated with TiN, and it		

	can be seen that the portion with TiN coating is the worst case in terms of biocompatibility. Thus, the safety of the raw material is demonstrated. This product is sterilized by the user by the method described in the user manual.

Device Name	**Subject Device**	**Predicate Device**	
Manufacturer	SHINHUNG MST CO., LTD.	Osstem Implant Co., Ltd.	SHINHUNG MST CO., LTD.
Device Name	Angled Abutment	ComOcta Angled Abutment	Angled Abutment
Design			
510(k) Number	K221752	K120847	K123155 / K160106
Angle (°)	15, 20	15, 20	15, 25
Diameter(mm)	3.7, 4.8	4.8, 6.0	4.6, 5.6
Material	Pure Titanium Gr 4 (ASTM F67)	Titanium Alloy Ti-6Al-4V (ASTM F136)	Pure Titanium Gr 4 (ASTM F67)
Sterilization	User sterile	User sterile	User sterile
S.E.	This product has the same purpose as the predicate device and has a size within the product size range of Osstem. The raw material is the same as the predicate device (K123155). In addition, it is manufactured through the same manufacturing process as our Luna Dental Implant System. Our previously approved product, Luna Dental Implant System (k123155), uses the same raw materials as the applied product, but only a part of it is coated with TiN. However, the whole is not coated with TiN, and it can be seen that the portion with TiN coating is the worst case in terms of biocompatibility. Thus, the safety of the raw material is demonstrated. This product is sterilized by the user by the method described in the user manual.		

Device Name	**Subject Device**	**Predicate Device**	
Manufacturer	SHINHUNG MST CO., LTD.	Osstem Implant Co., Ltd.	SHINHUNG MST CO., LTD.
Device Name	Temporary Abutment	ComOcta Temporary Abutment	Temporary Abutment
Design			
510(k) Number	K221752	K120847	K123155
Diameter (mm)	5.3, 6.5	4.8, 6.0	4.1, 4.6

Gingiva Height (mm)	1.0	0, 2.0	1.0, 3.0
Length (mm)	12.25, 13.55	10.0, 12.0	12.5, 12.6, 14.5, 14.6 *The following size configurations are not included. · 4.1mm diameter x all gingiva height x 12.5mm length. · 4.1mm diameter x all gingiva height x 14.5mm length. · 4.6mm diameter x all gingiva height x 12.6mm length. · 4.6mm diameter x all gingiva height x 14.6mm length.
Material	Pure Titanium Gr 4 (ASTM F67)	Titanium Alloy Ti-6Al-4V (ASTM F136)	Pure Titanium Gr 4 (ASTM F67)
Sterilization	User sterile	User sterile	User sterile
S.E.	This product has the same purpose as the predicate device and has a size within the product size range of Osstem. The raw material is the same as the predicate device (K123155). In addition, it is manufactured through the same manufacturing process as our Luna Dental Implant System. Our previously approved product, Luna Dental Implant System (k123155), uses the same raw materials as the applied product, but only a part of it is coated with TiN. However, the whole is not coated with TiN, and it can be seen that the portion with TiN coating is the worst case in terms of biocompatibility. Thus, the safety of the raw material is demonstrated. This product is sterilized by the user by the method described in the user manual.		

- Screw

Device Name	**Subject Device**	**Predicate Device**	
Manufacturer	SHINHUNG MST CO., LTD.	Osstem Implant Co., Ltd.	SHINHUNG MST CO., LTD.
Device Name	Cover Screw	Cover Screw	Cover Screw
Design			
510(k) Number	K221752	K120847	K123155
Material	Pure Titanium Gr 4 (ASTM F67)	Pure Titanium Gr 4 (ASTM F67)	Pure Titanium Gr 4 (ASTM F67)
Length (mm)	7.3	6.45	5.3, 5.95
Diameter (mm)	6.15	4.8, 6.0	2.84, 3.37

Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile
S.E.	This product has the same purpose as the predicate device and has a size within the product size range of Osstem. The raw material is the same as the predicate device (K123155). In addition, it is manufactured through the same manufacturing process as our Luna Dental Implant System. This product is sterilized by the user by the method described in the user manual.		

Device Name	**Subject Device**	**Predicate Device**	
Manufacturer	SHINHUNG MST CO., LTD.	Osstem Implant Co., Ltd.	SHINHUNG MST CO., LTD.
Device Name	Closing Screw	Closing Screw	Cover Screw

Design			
510(k) Number	New device	K120847	K123155
Material	Pure Titanium Gr 4 (ASTM F67)	Pure Titanium Gr 4 (ASTM F67)	Pure Titanium Gr 4 (ASTM F67)
Length (mm)	5.5	6.45	5.3, 5.95
Diameter (mm)	5.0	4.8, 6.0	2.84, 3.37
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile
S.E.	This product has the same purpose as the predicate device and has a size within the product size range of Osstem. The raw material is the same as the predicate device (K123155). In addition, it is manufactured through the same manufacturing process as our Luna Dental Implant System. This product is sterilized by the user by the method described in the user manual.		

Device Name	**Subject Device**	**Predicate Device**	
Manufacturer	SHINHUNG MST CO., LTD.	Osstem Implant Co., Ltd.	SHINHUNG MST CO., LTD.
Device Name	Abutment Screw	Ti Screw	
Design			
510(k) Number	K221752	K120847	K123155
Material	Titanium Alloy Ti-6Al-4V (ASTM F136)	Titanium Alloy Ti-6Al-4V (ASTM F136)	Titanium Alloy Ti-6Al-4V (ASTM F136)
Length (mm)	8.0	6.75	8.35, 8.7, 10.0
Diameter (mm)	2.5	2.5	2.17, 2.32
Sterilization	User sterile	User sterile	User sterile
S.E.	This product has the same purpose as the predicate device and has a size within the product size range of Osstem. The raw material is the same as the predicate device (K123155). In addition, it is manufactured through the same manufacturing process as our Luna Dental Implant System. This product is sterilized by the user by the method described in the user manual.		

8. Non-Clinical Testing

- Fatigue test was performed in accordance with ISO 14801.
- The following tests were evaluated under the 510k mentioned below. These predicate devices are made by our company and the subject device is made of the same material

and goes through the same manufacturing processes.

i. SLA Surface treatment (K123155 and K160106)
ii. Biocompatibility (K123155)
iii. Shelf Life (K123155)
iv. Sterilization (K123155)
    1. Gamma radiation method
    2. Moist Heat Method
v. Packaging (K123155)

- Endotoxin/LAL testing will be conducted on every batch of the subject device.
- A non-clinical worst-case MRI review was conducted to evaluate the Stella in an MRI environment using scientific evidence and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795). Titanium Grade 4 was assessed according to magnetic induction displacement force (ASTM F2052), magnetic induction torque (ASTM F2213), RF induction heating (ASTM F2182), and image artifact (ASTM F2119) by T. O. Woods et al. Based on that rationale, we have addressed parameters per FDA guidance " Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetic induced displacement force and torque.

9. Conclusion

The subject devices and the predicate device have the same intended use and have the same technological characteristics.

Overall, the Stella has the following similarities to the predicate device:

- have the same intended use,
- use the same operating principle,
- incorporate similar design,
- incorporate the same material and the sterilization method
- similar fatigue testing results to the predicate devices in the market.

Based on the similarities, we conclude that the Stella is substantially equivalent to the predicate devices.