



Food and Drug Administration
10903 New Hampshire Avenue
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Southern Implants (Pty) Ltd
% Yolanda Smith
Consultant
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114

June 13, 2017

Re: K163060

Trade/Device Name: Deep Conical (DC) Implants and Accessories
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: May 11, 2017
Received: May 11, 2017

Dear Yolanda Smith:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Mary S. Runner -A

Lori A. Wiggins, MPT, CLT

Acting Director

Division of Anesthesiology,

General Hospital, Respiratory,

Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K163060

Device Name

Deep Conical (DC) Implants and Accessories

Indications for Use (Describe)

Southern Implants Dental Implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols:

- replacing single and multiple missing teeth in the mandible and maxilla,
- immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge,
- immediate loading in all indications, except in single tooth situations on implants shorter than 8mm or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate.

The intended use for 3.0 Deep Conical implants is limited to replacement of maxillary lateral incisors and mandibular incisors

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)

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510(k) Summary

Sponsor:

Company Name: Southern Implants (Pty) Ltd.

Company Address: 1 Albert Road
Irene, South Africa 0062

Telephone: 011 27 12 667 1046

Fax: 011 27 12 667 1029

Contact Person: Lauranda G. Breytenbach

Summary Preparation Date: June 12, 2017

Device Name:

Trade Name: Deep Conical (DC) Implants and Accessories

Common/Usual Name: Dental Implants

Classification Name: Endosseous dental implant

Regulation Number: 21 CFR 872.3640

Product Codes: DZE and NHA

Device Class: Class II

Predicate Devices:

Predicate #	Manufacturer	Device Name	K Number
Primary 1	Astra Tech AB	OsseoSpeed EV (Previously known as OsseoSpeed Plus)	K120414
2	Northern Implants	Endosseous Implants and Accessories	K052490
3	Southern Implants, Inc	Endosseous dental implant system	K070905
4	Rhein '83 Srl	OT Equator	K142211
5	Southern Implants, Inc	Endosseous dental implant system	K053478
6	NSI Inc	Endosseous dental implant system	K070841

Device Description:**Implants**

The Deep Conical (DC Implant) has a deep conical connection system. The implants are available in the following configurations.

Description	Code	Lengths (mm)	Diameters (mm)
Deep Conical Cylindrical Implants	DCC	11 – 15	ø3.0
		8 – 15	ø3.5
		6 – 15	ø4.0
		9 – 15	ø5.0
Deep Conical Tapered Implants	DCT	9 – 15	ø3.0
		8 – 15	ø3.5
		6 – 15	ø4.0
		9 – 15	ø5.0
Deep Conical 12° Co-Axis Cylindrical Implants	DCC-12d	8 – 15	ø3.5
		8 – 15	ø4.0
Deep Conical 12° Co-Axis Tapered Implants	DCT-12d	8 – 15	ø3.5
		8 – 15	ø4.0

The implants have a moderately roughened surface. The implant is non-roughened around the coronal region of the implant. The implant has an external thread and microthreads at the coronal end of the implant. The Co-Axis Implants (Cylindrical, Tapered) are only to be compatible with the straight abutments.

Abutments

The following abutments are included to be used with the Deep Conical Implants.

Abutment Models	Abutment Connection Platform	Diameters (mm)	Angulation (°)	Lengths (mm)
Cover Screw	Deep conical	ø3.0, ø3.5, ø4.0 ø5.0	0	0.25

Healing Abutments	Deep conical	Ø3.0 – Ø5.0	0	2.2, 4.2, 6.2
Overdenture Abutments	Deep conical	Ø3.0 – Ø5.0	0	2, 4, 6
Temporary Cylinders	Deep Conical – Engaging and non-engaging	Ø3.0 – Ø5.0	0	10, 16
Cosmetic Abutments	Deep conical	Ø3.0 – Ø5.0	0, 12, 24	8.6, 8.4, 8.25
Gold Cylinders	Deep Conical	Ø3.0 – Ø5.0	0	13
Compact Conical Abutments	Deep Conical – Engaging and non-engaging	Ø3.0 – Ø5.0	0	1.5, 3, 4, 5
Passive Abutments	Deep Conical – Engaging and non-engaging	Ø3.0 – Ø5.0	0	11

Indications for Use

Southern Implants Dental Implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols:

- replacing single and multiple missing teeth in the mandible and maxilla,
- immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge,
- immediate loading in all indications, except in single tooth situations on implants shorter than 8mm or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate.

The intended use for 3.0 Deep Conical implants is limited to replacement of maxillary lateral incisors and mandibular incisors

Comparison of Technical Characteristics

IMPLANTS

Device and Manufacturer	New device	Predicate 1 (Primary)	Predicate 2
	Southern Implants Deep Conical (DC) Implants and accessories	Dentsply OsseoSpeed EV (Previously Plus) dental implant and abutment	Northern Implants Endosseous Implant and accessories

K Number		K120414	K052490
Brand Name	Deep Conical Implants and accessories	OsseoSpeed EV (Previously OsseoSpeed Plus)	Endosseous implants and accessories
Product Code	DZE	DZE	DZE
Regulation Number	878.3640	878.3640	878.3640
Review Panel	Dental	Dental	Dental
Regulation Name	Implant, endosseous, root form	Implant, endosseous, root form	Implant, endosseous, root form
Indications for Use	Southern Implants Dental Implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols: • replacing single and multiple missing teeth in the mandible and maxilla, • immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge, • immediate loading in all indications, except in single tooth situations on implants shorter than 8mm or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate.	The ASTRA TECH Dental implants are intended for both one- and two stage surgical procedures in the following situations and with the following clinical protocols: - Replacing single or multiple missing teeth in the mandible and maxilla. - Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge. - Especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective. - Immediate loading in all indications, except in single tooth situations on implants shorter than 8 mm or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate. The intended use for Osseospeed Plus 3.0 S is limited to replacement of maxillary lateral incisors and mandibular incisors.	Southern Implants dental implants are intended to be implanted in the upper and lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses or full arch prostheses. It further adds the option for immediate placement, and function on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

	The intended use for 3.0 Deep Conical implants is limited to replacement of maxillary lateral incisors and mandibular incisors		
Intended Use	Bone anchored Dental prosthetic	Bone anchored Dental prosthetic	Bone anchored Dental prosthetic
Anatomical Site	Mandible and Maxilla	Mandible and Maxilla	Mandible and Maxilla
Material	Grade 4 titanium (ASTM F67)	Grade 4 titanium (ASTM F67)	Grade 4 titanium (ASTM F67)
Implant surface	Southern Implants' roughened surface	TiOblast surface	Southern Implants' roughened surface
Sterility	Sterile	Sterile	Sterile
Connection system	Deep Conical	Deep Conical	N/A
Flutes	2	2	N/A
Body type	Threaded with microthreads at the coronal end of the implant	Threaded with microthreads at the coronal end of the implant	Threaded

Cylindrical Implants

Device and Manufacturer	New device	Predicate 1 (K120414)
	Southern Implants Deep Conical (DC) Implants and accessories	Dentsply OsseoSpeed EV dental implant and abutment
Part name	DCC	OsseoSpeed EV
Body lengths (mm)	6.1; 8; 9; 11; 13; 15	6; 8; 9; 11; 13; 15; 17
Diameters (mm)	ø3.02; ø3.52; ø4.00 and ø5.00.	ø3.0; ø3.6; ø4.2, ø4.8 and ø5.4.
Body Profile	Cylindrical (Straight)	Straight

Tapered Implants

Device and Manufacturer	New device	Predicate 1 (K120414)
	Southern Implants Deep Conical (DC) Implants and accessories	Dentsply OsseoSpeed EV dental implant and abutment
Part name	DCT	OsseoSpeed EV
Body lengths (mm)	6.1; 8; 9; 11; 13; 15	6; 8; 9; 11; 13; 15; 17
Diameters (mm)	ø3.02; ø3.52; ø4.00 and ø5.00.	ø3.0; ø3.6; ø4.2, ø4.8 and ø5.4.
Body Profile	Tapered	Straight

Co-Axis Implants: Cylindrical

Device and Manufacturer	New device	Predicate 1 (K120414)	Predicate 2 (K052490)
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	Southern Implants Deep Conical (DC) Implants and accessories	Dentsply OsseoSpeed EV dental implant and abutment	Northern Implants Endosseous Implant and accessories
Part name	DCC-12d	OsseoSpeed EV	BAT12d and BBBT12d
Body lengths (mm)	8; 9; 11; 13; 15	6; 8; 9; 11; 13; 15; 17	10; 11.5; 13; 15; 18 mm
Diameters (mm)	ø3.52 and ø4.00	ø3.0; ø3.6; ø4.2, ø4.8 and ø5.4.	ø5.0
Top Angle	12°	0°	12°
Body Profile	Cylindrical (Straight)	Straight	Tapered

Co-Axis Implants: Tapered

Device and Manufacturer	New device	Predicate 1 (K120414)	Predicate 2 (K052490)
	Southern Implants Deep Conical (DC) Implants and accessories	Dentsply OsseoSpeed EV dental implant and abutment	Northern Implants Endosseous Implant and accessories
Part name	DCT-12d	OsseoSpeed EV	BAT12d and BBBT12d
Body lengths (mm)	8; 9; 11; 13; 15	6; 8; 9; 11; 13; 15; 17	10; 11.5; 13; 15; 18 mm
Diameters (mm)	ø3.52 and ø4.00	ø3.0; ø3.6; ø4.2, ø4.8 and ø5.4.	ø5.0 and ø6.0
Top Angle	12°	0°	12°
Body Profile	Tapered	Straight	Tapered

ACCESSORIES: COVER SCREWS

Device and Manufacturer	New device	Predicate 1 (K120414)
	Southern Implants Deep Conical (DC) Implants and accessories	Dentsply OsseoSpeed EV dental implant and abutment
Material	Grade 4 commercially pure Titanium (ASTM F67)	Titanium
Surface	Smooth, machined (N6)	Smooth, machined (N6)
Sterility	Sterile	Sterile
Single use	Yes	Yes

Device and Manufacturer	New device	Predicate 1 (K120414)
	Southern Implants Deep Conical (DC) Implants and accessories	Dentsply OsseoSpeed EV dental implant and abutment
Part name	CS-DC3/4/5	25280/1/2/3

ACCESSORIES: HEALING ABUTMENTS

Healing Caps

Device and Manufacturer	New device	Predicate 3 (K070905)
	Southern Implants Deep Conical (DC) Implants and accessories	Southern Implants Inc, Endosseous implant and accessories
Material	Grade 5 Titanium Alloy (ASTM F136)	Stainless Steel 303
Surface	Smooth, N6	Smooth, N6
Sterility	Sterile	Sterile
Single use	Yes	Yes

Device and Manufacturer	New device	Predicate 3 (K070905)
	Southern Implants Deep Conical (DC) Implants and accessories	Endosseous implant and accessories
Part name	HMC HMCW HMCT7 HMCTW9	HMC HMCT7
Abutment length	4.60; 6.20 mm	4.60; 6.20 mm
Platform diameter	ø4.8; ø6.0; ø7.0; and ø9.0 mm	ø4.8 and ø7.0

Healing abutments

Device and Manufacturer	New device	Predicate 1 (K120414)
	Southern Implants Deep Conical (DC) Implants and accessories	Dentsply OsseoSpeed EV dental implant and abutment
Material	Grade 3 or 4 Titanium (ASTM F67)	Titanium
Surface	Smooth, N6	Smooth, N6
Sterility	Sterile	Sterile

Device and Manufacturer	New device	Predicate 1 (K120414)
	Southern Implants Deep Conical (DC) Implants and accessories	Dentsply OsseoSpeed EV dental implant and abutment

Part name	HA-DC3-2/4 HA-DC3-W-2/4/6 HA-DC4-N2 HA-DC4-4/6 HA-DC4-W-2/4/6 HA-DC5-2/4/6 HA-DC5-W-2/4/6	HealDesign EV
Abutment length	2.2; 4.2; 6.2 mm	2.5; 3.5; 4.5; 6.5 mm
Platform Diameter	ø3.5; ø4.0; ø4.5; ø5.5; ø6.5 mm	ø3.5; ø4.0; ø5.0; ø6.5; ø7.5 mm

ACCESSORIES: OVERDENTURE ABUTMENTS

Device and Manufacturer	New device	Predicate 4 (K142211)
	Southern Implants Deep Conical (DC) Implants and accessories	Rhein '83 OT Equator
Material	Grade 5 Titanium Alloy (ASTM F136)	Grade 5 Titanium Alloy (ASTM F136)
Surface	N6 Smooth, Titanium Nitride Coating	N6 Smooth, Titanium Nitride Coating
Sterility	Sterile	Non-Sterile
Single use	Yes	Yes

Device and Manufacturer	New device	Predicate 4 (K142211)
	Southern Implants Deep Conical (DC) Implants and accessories	Rhein '83 OT Equator
Part name	EQ-DC	OT Equator Abutment
Head diameter	ø2.5 mm	ø2.5 mm
Head height	1.4mm	2.0 mm
Collar heights	2; 3; 4; 5 mm	1 - 7 mm

ACCESSORIES: TITANIUM ABUTMENTS

Device and Manufacturer	New device	Predicate 1 (K120414)
	Southern Implants Deep Conical (DC) Implants and accessories	Dentsply OsseoSpeed EV dental implant and abutment
Material	Grade 3 or 4 Titanium (ASTM F67)	Titanium
Sterility	Sterile	Sterile
Single use	Yes	Yes

Device and Manufacturer	New device	Predicate 1 (K120414)
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	Southern Implants Deep Conical (DC) Implants and accessories	Dentsply OsseoSpeed EV dental implant and abutment
Part name	TC-DC3-1; TC-DC4-1; TC-DC5-1; TC-NDC3-1; TC-NDC4-1; TC-NDC5-1; TMC-1; TMC-5; TMCW-1; TMCW-5; TCA-DC3; TCA-DC4; TCA-DC5;	Temp Abutment EV; TiDesign; Direct Abutment EV; Titanium base; Uni Abutment
Collar height	1; 1.5; 1.875; 5 mm	1 - 5 mm
Restorative platform diameter	ø3.4; 4.1; 4.2; 4.4; 4.6; 5.0; 5.2; 5.6 mm	ø3.3; 4.0; 4.5; 4.7 5.0; 5.1 5.5; 6.0; 7.0 mm
Surface	Knurled and smooth	Knurled and smooth
Interface	Engaging and non-engaging	One position; six position; index free

Angled abutments

Device and Manufacturer	New device	Predicate 1 (K120414)
	Southern Implants Deep Conical (DC) Implants and accessories	Dentsply OsseoSpeed EV dental implant and abutment
Part name	TCA12-DC3; TCA12-DC4; TCA12-DC5; TCA24-DC3; TCA24-DC4; TCA24-DC5	TiDesign EV
Collar height	1.5mm	1.5 mm
Restorative platform diameter	ø4.20; 4.60 and 5.60 mm	ø4.0; 4.5; 5.5; 7.0 mm
Surface	Smooth	Smooth
Angulation	12 ° and 24 °	15 ° and 20 °

ACCESSORIES: GOLD CYLINDERS

Device and Manufacturer	New device	Predicate 5 (K053478)
	Southern Implants Deep Conical (DC) Implants and accessories	Southern Implants Inc, Endosseous implant and accessories
Material	Ceramicor or Deringer Ney Alloy 6019 with Acetal sleeve	Ceramicor with acetal sleeve
Sterility	Non-Sterile	Non-Sterile
Single use	Yes	Yes

Device and Manufacturer	New device	Predicate 4 (K053478)
	Southern Implants Deep Conical (DC) Implants and accessories	Southern Implants Inc, Endosseous implant and accessories

Part name	GC-DC3; GC-DC4; GC-DC5; GC-NDC3; GC-NDC4; GC-NDC5; GMC-1; GMCW-1	GC-EX-34; GMC-1
Collar length	1.0 mm	1.0 mm
Restorative platform diameter	ø3.4; 3.82; 4.1; 4.5; 4.55 mm	ø3.82; 4.0 mm
Surface	Knurled	Knurled
Interface	Engaging and non-engaging	Engaging and non-engaging

ACCESSORIES: COMPACT CONICAL ABUTMENTS

Device and Manufacturer	New device	Predicate 6 (K070841)
	Southern Implants Deep Conical (DC) Implants and accessories	NSI Inc, Endosseous implant and accessories
Material	Grade 5 Titanium Alloy (ASTM F136)	Grade 5 Titanium Alloy (ASTM F136)
Surface	Smooth	Smooth
Sterility	Sterile	Sterile
Single use	Yes	Yes

Device and Manufacturer	New device	Predicate 6 (K070841)
	Southern Implants Deep Conical (DC) Implants and accessories	NSI Inc, Endosseous implant and accessories
Part name	MC-DC3; MC-DC4; MC-DC5	AMCZ1
Abutment length	1.5; 3.0; 4.0 and 5.0 mm	1.5 mm
Restorative platform diameter	ø4.80 and 6.0 mm	ø4.05 mm

ACCESSORIES: PASSIVE ABUTMENTS

Device and Manufacturer	New device	Predicate 5 (K053478)
	Southern Implants Deep Conical (DC) Implants and accessories	Southern Implants Inc, Endosseous implant and accessories
Material	Sleeve: acetal or delrin Cylinder: grade 4 titanium (ASTM F67) Screw: Peek	Sleeve: acetal or delrin Cylinder: grade 4 titanium (ASTM F67) Screw: Peek
Surface	Smooth	Smooth
Sterility	Non-sterile	Sterile
Single use	Yes	Yes

Device and Manufacturer	New device	Predicate 5 (K053478)
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	Southern Implants Deep Conical (DC) Implants and accessories	Southern Implants Inc, Endosseous implant and accessories
Part name	PA-MC-48, SB16; SB-17-TT; SBV16; SBV-17-TT	PA-MC-48, SB16; SB-17-TT
Collar Height	1.0; 2.7 mm	1.6; 2.7 mm
Restorative platform diameter	ø3.4; 4.1; 4.5; 4.8; 6.0	ø4.8; 4.1; 4.3mm

Nonclinical Testing and Performance Testing

Non-clinical testing data provided or referenced to demonstrate substantial equivalence included detailed:

- Fatigue testing in accordance with ISO 14801 to prove that the implants are sufficiently strong enough for their intended purpose. Fatigue testing was substantially equivalent to the predicate devices.
- Comparative surface area, pullout strength and bone to implant contact analyses for implants less than 7mm in length was substantially equivalent to the predicate devices.
- Placement torque testing results were included to show that the implants are sufficiently strong enough to withstand the torque applied to them during placement. Torque testing was substantially equivalent to the predicate devices.
- The sterilization method for the subject devices is the same as the predicate. The sterilization method is Gamma radiation for the devices supplied sterile and has been validated in accordance with ISO 11137. The sterilization method is moist heat for the devices to be end user sterilized and has been validated in accordance with ISO 17665-1 and ISO 17665-2.
- The packaging for the subject device is the same as the predicate. Packaging was validated in accordance with ISO 11607. Accelerated aging per ASTM-F-1980 has been applied on the final packaging followed by validating durability to peel and dye tests conditions, in order to substantiate 5 years shelf life.
- The subject device is manufactured from the same material using the same manufacturing method as the applicant's own predicates (K070841, K070905, K053478, K052490), has the same intended use, and the same patient contact type and duration. The subject device is biocompatible in accordance with ISO 10993-1.

Clinical Studies

No clinical studies were conducted.

Final Conclusion

Southern Implants Deep Conical Implant range are substantially equivalent to the predicate devices in:

- Indication for use;
- Intended use;
- Anatomical site;
- Material;
- Sterility;
- Connection interface;
- Body type and flutes;
- Lengths and diameters

The indications for use are considered substantially equivalent to the primary predicate. The only difference is the subject device is less restrictive and does not include an indication for soft bone applications based on implant surface treatment. The only design differences are the roughened surfaces and the geometry of the implants. Tapered and co-axis implants are substantially equivalent to other devices already on the market. These differences are therefore not considered to be significant.

The Southern Implants Deep Conical Accessories which includes abutments and cover screws are substantially equivalent to the predicate devices in intended use as support accessories for prosthetic restorations. Technological characteristics are substantially equivalent to the predicates.

Based on the information contained in this submission Southern Implants thus concludes that the device is substantially equivalent to the predicate devices.