



September 24, 2024

ResMed Pty Ltd
% Sheila Bruschi
Senior Director
ReMed Corp
9001 Spectrum Center Boulevard
San Diego, California 92123

Re: K234134

Trade/Device Name: AirFit F30i Mask System; AirFit F30i NM Mask System; Arcadia Mask System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: December 29, 2023
Received: August 21, 2024

Dear Sheila Bruschi:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Rachana Visaria -S

Rachana Visaria, Ph.D.

Assistant Director

DHT1C: Division of Anesthesia,

Respiratory, and Sleep Devices

OHT1: Office of Ophthalmic, Anesthesia,

Respiratory, ENT, and Dental Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K234134

Device Name

AirFit F30i Mask System, AirFit F30i NM Mask System, Arcadia Mask System

Indications for Use (Describe)

AirFit F30i Mask System

The AirFit F30i mask has two product variants:

- AirFit F30i mask is intended for single-patient reuse in the home environment.
 - AirFit F30i SLM (Sleep Lab Mask) variant is intended for multi-patient reuse in the hospital/institutional environment.
- Both masks are intended for patients weighing more than 66lb (30kg), who have been prescribed non-invasive CPAP or bi-level positive airway pressure (PAP) therapy. The Sleep Lab Mask is the only variant that is validated and intended for multi-patient reprocessing and must be reprocessed if reused between patients.

AirFit F30i NM Mask System

The AirFit F30i Non Magnetic mask has two product variants:

- The AirFit F30i Non Magnetic variant is intended for single-patient reuse in the home environment.
- The AirFit F30i Non Magnetic SLM (Sleep Lab Mask) variant is intended for multi-patient reuse in the hospital/institutional environment.

This mask is for patients weighing more than 66 lb (30 kg), who have been prescribed non-invasive CPAP or bi-level positive airway pressure (PAP) therapy. The Sleep Lab Mask is the only variant that is validated and intended for multi-patient reprocessing and must be reprocessed if reused between patients.

Arcadia Mask System

The Arcadia has two product variants:

- Arcadia mask is intended for single-patient reuse in the home environment.
- Arcadia SLM (Sleep Lab Mask) variant is intended for multi-patient reuse in the hospital/institutional environment.

These masks are intended for patients weighing more than 66 lb (30kg), who have been prescribed non-invasive CPAP or bi-level positive airway pressure (PAP) therapy. The Sleep Lab Mask is the only variant that is validated and intended for multi-patient reprocessing and must be reprocessed if reused between patients.

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.

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510(k) Summary [As required by 21 CFR 807.92(c)]

Date Prepared:	24 September 2024
Company Name/Owner:	ResMed Pty Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW, 2153 Australia
Prepared and Submitted by:	Ms. Shu-Ying Huang Regulatory Affairs Manager Shuying.huang@resmed.com.sg
Official Contact:	Ms. Sheila Bruschi Senior Director, Regulatory Affairs ResMed Corp. 9001 Spectrum Center Blvd San Diego CA 92123 USA Tel +1 858 836 5934 sheila.bruschi@resmed.com
Device Trade Name:	AirFit F30i Mask System, AirFit F30i NM Mask System, Arcadia Mask System
Device Common Name:	Vented Full Face Mask
Classification and Classification Name:	21 CFR 868.5905, 73 BZD (Class II) Accessory to Noncontinuous Ventilator (IPPB)
Product Code:	BZD
Predicate Device:	Moore Park Mask (K183512)
Submission Reason:	• Changes being effected • New device

Device description:

The AirFit F30i, AirFit F30i NM and Arcadia mask systems are full-face conduit masks intended for use with Continuous Positive Airway Pressure (CPAP) and/or Bi-Level devices. CPAP & Bi-Level devices are used for the treatment of Obstructive Sleep Apnea (OSA) and/or non-life supporting ventilatory support. Both treatments deliver pressurized air from a flow generator to the patient. Such delivery of pressurized air relies on the Patient Interface; commonly known as the mask. Full face masks are a common type of Patient Interface (Mask) and are known to efficaciously support the delivery of pressurized air by providing a seal around the patient's nose and mouth.

The AirFit F30i, AirFit F30i NM and Arcadia mask systems each have two product variants:

- **AirFit F30i Mask/ AirFit F30i NM Mask/ Arcadia Mask:** This is the home use variant that is intended for single patient re-use.
- **AirFit F30i SLM/ AirFit F30i NM SLM/ Arcadia SLM** (sleep lab mask): This is the variant that is intended for multi-patient re-use and must be reprocessed if reused between patients using the disinfection guide

The AirFit F30i, AirFit F30i NM and Arcadia mask systems are made up of the following four main component assemblies: Cushion, conduit frame, elbow and headgear. The cushion and conduit frame are available in various sizes to allow for adequate mask fit over the intended patient population.

The AirFit F30i, AirFit F30i NM and Arcadia mask systems are prescription devices supplied non-sterile.

Compared to the predicate:

- AirFit F30i mask system labeling was revised with magnet-related contraindications and warnings,
- AirFit F30i NM mask system has no magnetic clips to enable usage of the device by patients who are now excluded from the intended users of the predicate due to new magnet-related contraindications and warnings,
- Arcadia mask system is a new design with magnetic clips.

Indications for use:**AirFit F30i Mask System**

The AirFit F30i mask has two product variants:

- AirFit F30i mask is intended for single-patient reuse in the home environment.
 - AirFit F30i SLM (Sleep Lab Mask) variant is intended for multi-patient reuse in the hospital/institutional environment.
- Both masks are intended for patients weighing more than 66lb (30kg), who have been prescribed non-invasive CPAP or bi-level positive airway pressure (PAP) therapy. The Sleep Lab Mask is the only variant that is validated and intended for multi-patient reprocessing and must be reprocessed if reused between patients.

AirFit F30i NM Mask System

The AirFit F30i Non Magnetic mask has two product variants:

- The AirFit F30i Non Magnetic variant is intended for single-patient reuse in the home environment.
- The AirFit F30i Non Magnetic SLM (Sleep Lab Mask) variant is intended for multi-patient reuse in the hospital/institutional environment.

This mask is for patients weighing more than 66 lb (30 kg), who have been prescribed non-invasive CPAP or bi-level positive airway pressure (PAP) therapy. The Sleep Lab Mask is the only variant that is validated and intended for multi-patient reprocessing and must be reprocessed if reused between patients.

Arcadia Mask System

The Arcadia has two product variants:

- Arcadia mask is intended for single-patient reuse in the home environment.
- Arcadia SLM (Sleep Lab Mask) variant is intended for multi-patient reuse in the hospital/institutional environment.

These masks are intended for patients weighing more than 66 lb (30kg), who have been prescribed non-invasive CPAP or bi-level positive airway pressure (PAP) therapy. The Sleep Lab Mask is the only variant that is validated and intended for multi-patient reprocessing and must be reprocessed if reused between patients.

Comparison table

Design parameter or feature	Predicate device K183512	Subject device K234134			Comments
	Moore Park Mask: (Commercial name AirFit F30i)	Modified device: AirFit F30i Mask System	Modified device: AirFit F30i NM Mask System	New device: Arcadia Mask System	
Indications for Use	The Moore Park mask is intended to be used by patients weighing more than 66 lb (30 kg) who have been prescribed non-invasive positive airway pressure (PAP) therapy such as CPAP or bi-level therapy. The mask is intended for single patient re-use in the home and multi-patient re-use in the hospital/institutional environment.	The AirFit F30i mask has two product variants: - AirFit F30i mask is intended for single-patient reuse in the home environment. - AirFit F30i SLM (Sleep Lab Mask) variant is intended for multi-patient reuse in the hospital/institutional environment. Both masks are intended for patients weighing more than 66lb (30kg), who have been prescribed non-invasive CPAP or bi-level positive airway pressure (PAP) therapy. The Sleep Lab Mask is the only variant that is validated and intended for multi-patient reprocessing and	The AirFit F30i Non Magnetic mask has two product variants: - The AirFit F30i Non Magnetic variant is intended for single-patient reuse in the home environment. - The AirFit F30i Non Magnetic SLM (Sleep Lab Mask) variant is intended for multi-patient reuse in the hospital/institutional environment. This mask is for patients weighing more than 66 lb (30 kg), who have been prescribed non-invasive CPAP or bi-level positive airway pressure (PAP) therapy. The Sleep Lab Mask is the only variant that is validated and intended for multi-patient reprocessing and must be reprocessed if reused between patients.	The Arcadia has two product variants: - Arcadia mask is intended for single-patient reuse in the home environment. - Arcadia SLM (Sleep Lab Mask) variant is intended for multi-patient reuse in the hospital/institutional environment. These masks are intended for patients weighing more than 66 lb (30kg), who have been prescribed non-invasive CPAP or bi-level positive airway pressure (PAP) therapy. The Sleep Lab Mask is the only variant that is validated and intended for multi-patient reprocessing and must be reprocessed if reused between patients.	Equivalent

Design parameter or feature	Predicate device K183512	Subject device K234134			Comments
	Moore Park Mask: (Commercial name AirFit F30i)	Modified device: AirFit F30i Mask System	Modified device: AirFit F30i NM Mask System	New device: Arcadia Mask System	
		must be reprocessed if reused between patients.			
Intended Use	The mask is intended to provide an interface for CPAP or bi-level devices.	The mask is intended to provide an interface for CPAP or bi-level devices.			Identical
FDA Product Code	BZD	BZD			Identical
Patient population	Patients weighing more than 66lb (30kg) for whom positive airway pressure therapy has been prescribed.	Patients weighing more than 66lb (30kg) for whom positive airway pressure therapy has been prescribed.			Identical
Environment of Use	Home or hospital/institutional environment.	Home or hospital/institutional environment.			Identical
Reprocessing claims	Single patient re-use or multi-patient re-use.	Single patient re-use or multi-patient re-use.			Identical
Sterility state as provided	Non-sterile	Non-sterile			Identical
Validated reprocessing methods	High-Level Thermal disinfection	High-Level Thermal disinfection			Identical
Cushion type	Oral nasal cradle cushion that seals under the nose and around the mouth	Oral nasal cradle cushion that seals under the nose and around the mouth		Oral pillows cushions that seals under the nose and around the mouth	Equivalent
Frame type	Tubular conduit	Tubular conduit			Identical

Design parameter or feature		Predicate device K183512		Subject device K234134				Comments
		Moore Park Mask: (Commercial name AirFit F30i)		Modified device: AirFit F30i Mask System	Modified device: AirFit F30i NM Mask System		New device: Arcadia Mask System	
PAP tubing connection point		22mm conical connector as per ISO 5356-1 over the head connection		22mm conical connector as per ISO 5356-1 over the head connection				Identical
Exhaust port location		Elbow and cushion		Elbow and cushion				Identical
Sizes		Cushion available in four sizes Frame available in three sizes Headgear available in one size		Cushion available in four sizes Frame available in three sizes Headgear available in one size		Pillows cushion available in three sizes Frame available in three sizes Headgear available in one size		Equivalent
Mask exhaust flow (Nominal)								ISO 17510:2015 Annex B
		Pressure (cm H ₂ O)	Flow (L/min) ‘Full Face’ curve	Pressure (cm H ₂ O)	Flow (L/min) ‘Full Face’ curve	Pressure (cm H ₂ O)	Flow (L/min) ‘Full Face’ curve	
		4	20	4	22	4	22	
		9	31	11	38	11	39	
		15	41	17	48	17	49	
		20	49	24	59	24	60	
		25	55	30	67	30	69	
CO ₂ re-breathing performance – Normal Condition ($<20\%$)	Pressure (cm H ₂ O)	Relative CO ₂ increase	Relative CO ₂ increase			Relative CO ₂ increase		ISO 17510:2015 Annex F
	4	8.1%	7.7%			Arcadia Mask	Arcadia SLM	
	5	5.8%	5.2%			9.9%	9.7%	
	10	1.9%	1.5%			8.5%	8.4%	
						6.3%	6.2%	

Design parameter or feature		Predicate device K183512	Subject device K234134				Comments										
		Moore Park Mask: (Commercial name AirFit F30i)	Modified device: AirFit F30i Mask System	Modified device: AirFit F30i NM Mask System	New device: Arcadia Mask System												
CO ₂ re-breathing performance – Single Fault Condition (<60%)	Fault	Relative CO ₂ increase	Relative CO ₂ increase		Relative CO ₂ increase		ISO 17510:2015 Annex F										
	Fault 1	32.6%	42.5%		Arcadia Mask	Arcadia SLM											
					42.8%	41.9%											
Fault 2	45.3%	55.1%		54.8%	54.3%												
Resistance to flow (Pressure drop across mask in cmH ₂ O)		<table><tr><td>@50 L/min</td><td>@100 L/min</td></tr><tr><td>0.2</td><td>1.0</td></tr></table>	@50 L/min	@100 L/min	0.2	1.0	<table><tr><td>@50 L/min</td><td>@100 L/min</td></tr><tr><td>0.2</td><td>1.0</td></tr></table>	@50 L/min	@100 L/min	0.2	1.0	<table><tr><td>@50 L/min</td><td>@100 L/min</td></tr><tr><td>0.3</td><td>1.2</td></tr></table>	@50 L/min	@100 L/min	0.3	1.2	ISO 17510:2015 Annex C
@50 L/min	@100 L/min																
0.2	1.0																
@50 L/min	@100 L/min																
0.2	1.0																
@50 L/min	@100 L/min																
0.3	1.2																
Breathing Resistance (cmH ₂ O)	Inspiratory	0.2	0.2				ISO 17510:2015 Annex E										
	Expiratory	0.3	0.4		0.2												
AAV Operating Pressures	Open-to-atmosphere pressure	≤ 4 cm H2O	< 4 cm H2O				Equivalent ISO 17510:2015 Annex D										
	Closed-to-atmosphere pressure	≤ 4 cm H2O	< 4 cm H2O				ISO 17510:2015 Annex D										
Flow generator setting on compatible ResMed CPAP		“Full face” (Air 10 devices)	“Full face” (Air 10 devices)				Identical										

Design parameter or feature		Predicate device K183512	Subject device K234134			Comments
		Moore Park Mask: (Commercial name AirFit F30i)	Modified device: AirFit F30i Mask System	Modified device: AirFit F30i NM Mask System	New device: Arcadia Mask System	
and Bi-level flow generators.						
Operating pressure range (cmH ₂ O)		4 - 25	4 – 30	4 – 30	4 – 30	Equivalent
Sound		Sound power level: 25 dBA Sound pressure level: 18 dBA	Sound power level: 25 dBA Sound pressure level: 18 dBA		<u>Multi-hole vent</u> Sound power level: 25 dBA Sound pressure level: 18 dBA <u>QuietAir vent</u> Sound power level: 22 dBA Sound pressure level: 15 dBA	Equivalent
Magnetic Clips	Number of magnets	4	4	0	4	Equivalent
	Strength (mT) on the surface	<400mT	<400mT	N/A	<400mT	
	Strength (mT) at 50 mm distance	<0.5 mT	<0.5 mT	N/A	<0.5 mT	
Operating and storage temperature		Operating temperature: 5°C to 40°C Storage temperature: -20°C to +60°C	Operating temperature: 5°C to 40°C Storage temperature: -20°C to +60°C			Identical

Non-clinical data submitted:

Non-clinical verification and validation assessment/testing demonstrated that AirFit F30i, AirFit F30i NM and Arcadia mask systems met all intended performance requirements. These included:

Applicable performance and safety tests in accordance with ISO 17510:2015 Medical devices -- Sleep apnoea breathing therapy -- Masks and application accessories:

- CO2 rebreathing (ISO 17510:2015 Annex F)
- Exhaust flow (ISO 17510:2015 Annex B)
- Resistance to flow (ISO 17510:2015 Annex C)
- Anti-Asphyxia valve operating pressures (ISO 17510:2015 Annex D)
- Breathing resistance (ISO 17510:2015 Annex E)
- Vibration and noise (ISO 17510:2015 Annex G)

Other bench tests:

- Pressure accuracy and pressure swing performance
- Mechanical Integrity of the mask system before and after the following environmental tests:
 - Home cleaning
 - Transportation and Storage
 - Operation environment
 - Free fall and sit test
 - Reprocessing

Biocompatibility evaluation was assessed and/or conducted in accordance with ISO 18562-1, ISO 10993-1 and applicable regulatory guidance.

Validation of reprocessing claims (in accordance with ISO 17664-1, ISO 17664-2, ST98 and AAMI TIR12) included a combination of cleaning efficacy, disinfection efficacy, residual toxicity and mechanical integrity assessment/testing.

Verification confirmed that the new device met the predetermined acceptance criteria and the performance is substantially equivalent to the previously cleared predicate AirFit F30i mask system (K183512).

Risk assessment activities, including tests of magnetic field strength, were conducted to assess the risk of magnetic interference from static magnetic fields for ResMed masks containing magnets with medical implants/devices and metallic implanted objects.

The AirFit F30i, AirFit F30i NM and Arcadia mask systems were assessed and/or tested in accordance with the applicable requirements in relevant FDA consensus standards including:

Standards	Title
ISO 17510:2015	Medical devices -- Sleep apnoea breathing therapy -- Masks and application accessories
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
ISO 18562-2:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 2: Tests for emissions of particulate matter

ISO 18562-3:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds (VOCs)
ISO 18562-4:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 4: Tests for leachables in condensate
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
ISO 10993-3:2014	Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Test for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices – Part 10: Tests for skin sensitization
ISO 10993-11:2017	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
ISO 10993-12:2021	Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials
ISO 10993-17:2002	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
ISO 17664-1:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices
ISO 17664-2:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices.
ISO 5356-1:2015	Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets
ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
ST98:2022	Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices
AAMI TIR12:2020	Designing, Testing, And Labeling Medical Devices Intended For Processing By Health Care Facilities: A Guide For Device Manufacturers

Substantial Equivalence Conclusion:

The AirFit F30i, AirFit F30i NM and Arcadia mask systems are substantially equivalent to the predicate K183512:

- They have equivalent intended use
- They have similar technological characteristics
- They have similar performance characteristics
- The differences do not raise any new questions of safety or effectiveness
- They are as safe and as effective as the predicate device