January 2, 2020

Invacare Corporation
Elijah Wreh
Regulatory Affairs Manager
One Invacare Way
Elyria, Ohio 44035

Re: K192216
Trade/Device Name: Invacare® Aviva FX Power Wheelchair, Model: IFX-20MP
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: December 5, 2019
Received: December 6, 2019

Dear Elijah Wreh:

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,

Heather Dean, Ph.D.
Acting Assistant Director, Acute Injury Devices
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K192216

Device Name
Invacare® AVIVA FX Power Wheelchair
Model: IFX 20MP

Indications for Use *(Describe)*
The Invacare® AVIVA FX Power Wheelchair is indicated to provide mobility and positioning to persons limited to a sitting position.

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 – K192216

Submitter Information per 21 CFR 807.92(a)(1)

SPONSOR:	Invacare Corporation One Invacare Way Elyria, OH 44035

PRIMARY CONTACT:	Elijah Wreh Regulatory Affairs Manager Phone: (440) 329-6840 Email: ewreh@invacare.com

MANUFACTURER:	Invacare Corporation 1200 Taylor Street Elyria, Ohio 44035

DATE PREPARED per 21 CFR 807.92(a)(1):	2 January 2020

Device Information per 21 CFR 807.92(a)(2)

NAME OF SUBJECT DEVICE:	Invacare® AVIVA FX Power Wheelchair Model: IFX 20MP

COMMON/USUAL NAME:	Power Wheelchair

CLASSIFICATION NAME:	Powered Wheelchair [21 CFR §890.3860]

REGULATORY CLASS:	2

PRODUCT CODE:	ITI: Wheelchair, Mechanical

PREDICATE DEVICES:	Primary: Invacare TDX SP2 Power Wheelchair (K170507) No reference devices were used in this submission.

Device Description per 21 CFR 808.92(a)(4)

The subject device is a front wheel drive version of the existing previously cleared Invacare TDX SP2 (Center Wheel Drive) Power Wheelchair (K170507) with LiNX Electronics and Ultra Low Maxx Seating System. The subject version of the Invacare TDX SP2 Power Wheelchair consists of the following changes:

- Alternative Front Wheel Drive Base
- Seating Brackets to connect the Ultra Low Maxx Seating System to the base
- Wiring Harness to connect the LiNX controller, the AVIVA FX base and the Ultra Low Maxx Seating System

The Invacare® AVIVA FX Power Wheelchair is a 24V DC battery-powered, motor-driven wheelchair, utilizing the predicate device LiNX® Control System and Ultra Low Maxx Seating System. The subject device consists of a rigid or "non-folding" type power wheelchair base with front wheel drive with 2 casters in the rear and two anti-tippers in the front. It is powered by two 12-volt DC batteries and two 4-pole single stage drive motors.

Each accessory connects to the LiNX Control system either directly by connecting to the LiNX communication bus (direct access) or indirectly by connecting to an Input module (indirect access).

The following components are equipped with wireless technology:

- Primary Driver Controls
- Direct Access
- Display Modules
- Indirect Access (via input module) – Wireless mouse emulator

The following components are not equipped with wireless technology:

- Power Modules
- Stability Control
- Indirect Access (via input module) – Compact
- Attendant Driver Controls
- Actuator Control
- Alternative Driver Controls (LiNX Electronic options)
- Input Module with Integrated Sip-n-Puff
- USB Charger Module

Intended Use per 21 CFR 807.92(A)(5)

The intended use of the device is to provide mobility and positioning to persons limited to a sitting position.

Indications for Use per FORM FDA 3881

The Invacare® AVIVA FX Power Wheelchair is indicated to provide mobility and positioning to persons limited to a sitting position.

Indications for Use Characteristics Comparison

Both the subject and predicate device share the same Indications for Use and Intended use.

Technological Characteristics Comparison with the predicate device per 21 CFR 807.92(a)(6)

The technological characteristics comparison demonstrates that the subject device is substantially equivalent in intended use, design, materials, and operational principles to the previously cleared predicate device.

Basis of Substantial Equivalence per 21 CFR 807.100(b)(2)(ii)(A)

The substantial equivalence of the subject device was determined as per the FDA guidance document, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" and the technological characteristics which include materials, design, energy source, and other device features, as defined in section 513(i)(1)(B) of the FD&C Act and 21 CFR 807.100(b)(2)(ii)(A).

The subject device is a modification to the previously cleared Invacare TDX SP2 Power Wheelchair (K170507) and contains the same components and features as the predicate device. The modification, use of a front wheel drive base does not raise new questions of safety and effectiveness.

The performance testing, device comparison, and dimensional analysis demonstrate that the subject device components and features are the same or substantially equivalent to the predicate device regarding the following:

- Static Stability
- Dynamic Stability of Electric Wheelchairs
- Effectiveness of Brakes
- Energy Consumption of Electric Wheelchairs and Scooters for Determination of Theoretical Distance Range
- Dimensions Mass and Maneuvering Space
- Maximum Speed Acceleration and Deceleration of Electric Wheelchairs
- Seating and Wheel Dimensions
- Methods for Static Impact and Fatigue Strengths
- Climatic Tests for Electric Wheelchairs

- Climbing Ability of Electrically Powered Wheelchairs
- Power and Control Systems for Electrically Powered Wheelchairs and Scooters
- Information Disclosure Documentation and Labeling
- Wheeled Mobility Devices for Use as Seats in Motor Vehicles
- Methods for Electromagnetic Compatibility of Electrically Powered Wheelchairs and Scooters and Battery Chargers
- Batteries and chargers for powered wheelchairs
- Software Life Cycle
- Flammability Testing
- Assessment of the Ignitability of Upholstered Furniture – Ignition Source Smoldering Cigarette
- Wireless Coexistence

The data generated from the subject Invacare® (front wheel drive) AVIVA FX Power Wheelchair design verification test reports support a finding of substantial equivalence regarding the device comparison, dimensional analysis, device specifications, design characteristics and to provide mobility and positioning to persons limited to a sitting position.

Indications for Use Comparison Table

Device	Subject Device Invacare® AVIVA FX Power Wheelchair	Predicate Devices Invacare TDX SP2 Power Wheelchair (K170507)
Indications for Use	The Invacare® AVIVA FX Power Wheelchair is indicated to provide mobility and positioning to persons limited to a sitting position.	The indication for use of the Invacare® TDX® SP2 Power Wheelchair is to provide mobility and positioning to persons limited to a sitting position.
Intended Use	To provide mobility and positioning to persons limited to a sitting position	To provide mobility and positioning to persons limited to a sitting position
Type of Use	Prescription (RX Only)	Prescription (RX Only)

Design and Technological Characteristics Comparison – Finished Device

Component	Description	Predicate Device Invacare® TDX SP2 Power Wheelchair (K170507)	Subject Device Invacare® AVIVA FX Power Wheelchair (K192216)
SEATING Ultra LowMaxx	Powered Positioning Configurations	Fixed, Tilt/Recline/Elevate, Tilt/Recline, Recline, Elevate, Tilt/Elevate, Tilt Only.	Tilt/Recline/Elevate
	Seat Widths	16” to 22”	16” to 22”
	Seat Depths	15” to 23”	15” to 23”
	Back Heights	18” to 25” (tilt) or 20” to 27” (tilt and recline)	18” to 25” (tilt) or 20” to 27” (tilt and recline)
	Upholstery	Meshtex, Startex, Spacetex, O-Vinyl, Polyester	Meshtex, Startex, Spacetex, O-Vinyl, Polyester
	Elevating Seat Range	12”	12”
	Tilt Range	50º	50º
	Recline Range	168º	168º
	Seat Cushion Accessories	Matrx Libra, Matrx PS, Matrx Vi, Matrx Flo-tech Lite and Contour	Matrx Libra, Matrx PS, Matrx Vi, Matrx Flo-tech Lite and Contour
	Back Types	High Back, Matrx PB, Matrx PB Elite, Matrx PB Deep and Matrx PB Elite TR	High Back, Matrx PB, Matrx PB Elite, Matrx PB Deep and Matrx PB Elite TR
	Back and Headrest Accessories	Motion Concepts standard, Elan standard, Elan Occipital, Elan 4-point and Motion Concepts Onyx	Motion Concepts standard, Elan standard, Elan Occipital, Elan 4-point and Motion Concepts Onyx
	Arm Types	<u>Tilt Armrests</u> Dual post adjustable, Ultra Rail mounted flip back cantilever Maxx tilt arm <u>Recline Armrests</u> Adjustable, Maxx style cane mounted straight and curved.	<u>Tilt Armrests</u> Dual post adjustable, Ultra Rail mounted flip back cantilever Maxx tilt arm <u>Recline Armrests</u> Adjustable, Maxx style cane mounted straight and curved.
	Armpads	Modular, Standard, Waterfall, Flat and Ergonomic	Modular, Standard, Waterfall, Flat and Ergonomic
	Leg Rest Types	Basic fixed center mount, Invacare Action fixed swing away receiver, Invacare 70º fixed swing away, LNX powered center mount, Maxx style	Basic fixed center mount, Invacare Action fixed swing away receiver, Invacare 70º fixed swing away, LNX powered center mount, Maxx style

Component	Description	Predicate Device Invacare® TDX SP2 Power Wheelchair (K170507)	Subject Device Invacare® AVIVA FX Power Wheelchair (K192216)
		powered swing away, Maxx style manual swing away, Heavy duty 70^{o} swing away.	powered swing away, Maxx style manual swing away, Heavy duty 70^{o} swing away.
	Leg Rest Accessories	Flip-up foot platform, Individual foot plates for center mount, Foot plate options for elevating and swing-away, Single foot plate options (adjustable and multi-axis adjustable, Heel loops, Calf panel	Flip-up foot platform, Individual foot plates for center mount, Foot plate options for elevating and swing-away, Single foot plate options (adjustable and multi-axis adjustable, Heel loops, Calf panel
	Laterals	Matrx standard fixed and offset fixed, Matrx swing away, Matrx Elite swing away, Matrx Offset Elite swing away, Matrx lateral trunk support with fixed mounting, Maxx Style swing-away	Matrx standard fixed and offset fixed, Matrx swing away, Matrx Elite swing away, Matrx Offset Elite swing away, Matrx lateral trunk support with fixed mounting, Maxx Style swing-away
	Hip Supports	Lateral, Lift-off removable, Maxx style quick release, Swing away removable	Lateral, Lift-off removable, Maxx style quick release, Swing away removable
CONTROL SYSTEM LiNX	System Name	LiNX Electronic	LiNX Electronic
	Cables	Variable cable lengths A range of standard cable lengths available	Variable cable lengths A range of standard cable lengths available
	System Architecture	Microprocessor Controlled	Microprocessor Controlled
	Non-Expandable Options	Yes	Yes
	Expandable Options	Yes	Yes
	Wireless Devices	Bluetooth	Bluetooth
	Power Source	24V nominal	24V nominal
	Bus Interface	CAN	CAN
POWER BASE	Base Configuration	Centre Wheel Drive	Front Wheel Drive
	Base Width	24” or 25.5” (depending on narrow/wide version)	24.3” (single option)
	Length (without leg rests)	31.5” to 45.3” (depending on seat configuration)	42.71”

Component	Description	Predicate Device Invacare® TDX SP2 Power Wheelchair (K170507)	Subject Device Invacare® AVIVA FX Power Wheelchair (K192216)
OTHER SPECIFICATIONS	Ground Clearance	> 2.5”	> 2.5”
	Batteries	GP24 Batteries	GP24 Batteries
	Braking System	Electro-mechanical Friction Brake	Electro-mechanical Friction Brake
	Drive Wheel Size	14” x 3”	14” x 3”
	Incline Capability	9º	9º
	Maximum Speed	5mph, or 5.8mph	6.25mph
	Motors	4-Pole SSD	4-Pole SSD
	Weight Capacity	300lbs.	300lbs.
	Suspension	Enhanced SureStep® Suspension	Four-bar linkage Independent Suspension System

Design Characteristics Comparison – LiNX® Electronics

Description	Predicate Device Invacare® TDX SP2 Power Wheelchair (K170507)	Subject Device Invacare® AVIVA FX Power Wheelchair (K192216)
System Name	LiNX	LiNX
Cables	Variable cable lengths A range of standard cable lengths available	Variable cable lengths A range of standard cable lengths available
System Architecture	Microprocessor Controlled	Microprocessor Controlled
Non-Expandable Options	Yes	Yes
Expandable Options	Yes	Yes
Wireless Devices	Bluetooth	Bluetooth
Power Source	24V nominal	24V nominal
Bus Interface	CAN	CAN

Design Characteristics Comparison – Seating

Description	Predicate Device Invacare® TDX® SP2 Power Wheelchair	Subject Device Invacare® AVIVA FX Power Wheelchair (K192216)
Seat Types	Fixed, Tilt/Recline/Elevate, Tilt/Recline, Recline, Elevate, Tilt/Elevate, Tilt Only.	Tilt/Recline/Elevate
Seat Widths	16” to 24”	16” to 24”
Seat Depths	16” to 23”	16” to 23”
Back Heights	18” to 25” (tilt only) or 20” to 27” (tilt and recline)	18” to 25” (tilt only) or 20” to 27” (tilt and recline)
Upholstery	Meshtex, Startex, Spacetex, O-Vinyl, Polyester	Meshtex, Startex, Spacetex, O-Vinyl, Polyester
Elevating Seat Range	12”	12”
Tilt Range	50^{o}	50^{o}
Recline Range	168^{o}	168^{o}

General Comparison of the Performance Characteristics Associated with the Control System

Description	Subject Device Invacare® TDX® SP2 Power Wheelchair (K170507)	Subject Device Invacare® AVIVA FX Power Wheelchair (K192216)
Cables	Variable cable lengths A range of standard cable lengths available	Variable cable lengths A range of standard cable lengths available
System Architecture	Microprocessor Controlled	Microprocessor Controlled
Non-Expandable Options	Yes	Yes
Expandable Options	Yes	Yes
Wireless Devices	Bluetooth	Bluetooth
Power Source	24V nominal	24V nominal
Bus Interface	CAN	CAN

Comparison of the Performance Characteristics Associated with the Enhanced Rehabilitation Primary Remotes

Description	Subject Device Invacare® TDX® SP2 Power Wheelchair (K170507)	Subject Device Invacare® AVIVA FX Power Wheelchair (K192216)
	REM400	REM400
Mounting	2 x M5 screws suitable for both tube and plate.	2 x M5 screws suitable for both tube and plate.
Connection	Direct	Direct
User Display	LCD – colour.	LCD – colour.
Viewable LCD Size	49 x 74mm	49 x 74mm
Joystick	Magnetic	Magnetic
Text & Graphics	Icons & translations. Customisable.	Icons & translations. Customisable.
Touch Interface	Yes – capacitive	Yes – capacitive
On/Off Button	Yes	Yes
Horn	Yes	Yes
Mode/Function	Button or Touch	Button or Touch
Programmable Multi-Function Keys	2 x Configurable	2 x Configurable
Jack Sockets	2 x Stereo.	2 x Stereo.
Speed Selection	Virtual speed dial operated by touch.	Virtual speed dial operated by touch.
Speed Indication	Yes	Yes
Number of Drive Functions	36	36
Battery Gauge	Bar on LCD (continuous)	Bar on LCD (continuous)
Seating Control	Up to 8 actuators	Up to 8 actuators
Lighting Control	Yes	Yes
Real Time Clock	Yes	Yes
Charger Port	XLR	XLR
Status Indicator	Error codes on display with supporting icons. Additional LED flash codes for faulty LCD.	Error codes on display with supporting icons. Additional LED flash codes for faulty LCD.
Mouse Mover	Yes. Built-in Bluetooth connection.	Yes. Built-in Bluetooth connection.
Remote Diagnostics	Built-in Bluetooth connection (Yes).	Built-in Bluetooth connection (Yes).

Performance Data

Non-Clinical Test per 21 CFR 807.92(b)(1)

International Organization of Standardization (ISO) testing, California Technical (CAL), American National Standards Institute (ANSI) and European (EN) standards testing were performed to demonstrate that the subject Invacare® AVIVA FX Power Wheelchair meet the performance requirements and is substantially equivalent to the predicate device identified throughout this submission and do not raise any new questions of safety and effectiveness.

Test Standard	Test Description
ISO 7176-1:2014	Wheelchairs Part 1: Determination of Static Stability
ISO 7176-2:2017	Wheelchairs Part 2: Determination of Dynamic Stability of Electrically Powered Wheelchairs
ISO 7176-3:2012	Wheelchairs Part 3: Determination of Effectiveness of Brakes
ISO 7176-4:2008	Wheelchairs Part 4: Energy Consumption of Electrical Wheelchairs and Scooters for Determination of Theoretical Distance Range
ISO 7176-5:2008	Wheelchairs Part 5: Determination of Dimensions, Mass and Maneuvering Space
ISO 7176-6:2018	Wheelchairs Part 6: Determination of Maximum Speed, Acceleration and Deceleration of Electric Wheelchairs
ISO 7176-7:1998	Wheelchairs Part 7: Measurement of Seating and Wheel Dimensions
ISO 7176-8:2014	Wheelchairs Part 8: Requirements and Test Methods for Static, Impact and Fatigue Strengths
ISO 7176-9:2009	Wheelchairs Part 9: Climatic Tests for Electric Wheelchairs
ISO 7176-10:2008	Wheelchairs Part 10: Determination of Obstacle Climbing Ability of Electrically Powered Wheelchairs
ISO 7176-11:2012	Wheelchairs Part 11: Test Dummies
ISO 7176-13:1989	Wheelchairs Part 13: Determination of Coefficient of Friction of Test Surface
ISO 7176-14:2008	Wheelchairs Part 14: Power and Control Systems for Electrically Powered Wheelchairs and Scooters – Requirements and Test Methods
ISO 7176-15:1996	Wheelchairs Part 15: Requirements for Information Disclosure, Documentation and Labeling
ISO 7176-16:2012	Wheelchairs Part 16: Resistance to Ignition of Postural Support Devices
ISO 7176-19:2008	Wheelchairs Part 19: Wheeled Mobility Devices for Use as Seats in Motor Vehicles
ISO 7176-21:2008	Wheelchairs Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
ISO 7176-22:2014	Wheelchairs Part 22: Set-up Procedures
ISO 7176-25:2013	Wheelchairs Part 25: Batteries and chargers for powered wheelchairs

Test Standard	Test Description
IEC 62304:2006	Medical Device Software – Software Life Cycle
CAL117: 2013, Section 1	Requirements, Test Procedure and Apparatus for Testing the Smolder Resistance of Materials Used in Upholstered Furniture
EN 1021-2:2014	Furniture Assessment of the Ignitability of Upholstered Furniture: Ignition Source: Match Flame Equivalent
ANSI C63.27	Wireless Coexistence

Performance Data Conclusions per 21 CFR 807.92(b)(3)

The subject device utilizes the same intended use, same material composition, and similar technological characteristics as the predicate device. The non-clinical laboratory data support the safety and performance of the subject device and demonstrate that any differences in technological characteristics do not raise any new questions of safety and effectiveness. Therefore, the subject Invacare® AVIVA FX Power Wheelchair is substantially equivalent to the predicate devices identified throughout this submission.

Software Verification Testing

Software Verification Testing was performed to evaluate the functionality of the design, materials, and operational principles of the subject device. Software verification testing was conducted on the subject device as recommended by the FDA's guidance document "FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005." and *IEC 62304:2006, Medical Device Software – Software Life Cycle*.

Level of Concern: The Level of Concern for the subject device software is moderate. This determination is based on answering the questions in the FDA Guidance Document "*FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005*." All of the questions related to a Major Level of Concern were answered "No." One question in the Moderate Level of Concern was answered "Yes" because "prior to mitigation of hazards, a failure of the Software Device could result in Minor Injury, either to a patient or to a user of the subject device

Biocompatibility Testing

The biocompatibility evaluation for the subject Invacare® AVIVA FX Power Wheelchair were conducted in accordance with the FDA Blue Book Memorandum #G95 − 1 "*Use of International Standard ISO − 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'*" May 1, 1995, and International Standard *ISO 10993 − 1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process*," as recognized by FDA. The battery of testing included the following tests:

- AAMI / ANSI / ISO 10993-5:2009, Biological Evaluation of Medical Devices - Part 5: Tests for *in vitro* Cytotoxicity

- AAMI / ANSI / ISO 10993-10:2010, Biological Evaluation of Medical Devices - Part 10: Tests for skin irritation

Animal Study

Animal testing was not required for this submission.

Clinical Testing

Clinical testing was not required for this submission.