July 1, 2020

Atrility Medical, LLC
% Gary Syring
Principal Consultant
Quality & Regulatory Associates, LLC
800 Levanger Lane
Stoughton, Wisconsin 53589

Re: K200674
Trade/Device Name: AtriAmp, AtriAmp - Pacing Cable Medtronic Connector, AtriAmp - Pacing Cable Oscor Connector
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer And Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: May 15, 2020
Received: May 15, 2020

Dear Gary Syring:

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,

Hetal Odobasic
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular 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)*
K200674

Device Name
AtriAmp

Indications for Use *(Describe)*

The AtriAmp supports pacing by acting as an extension cable between an external pacemaker and cardiac pacing leads. The AtriAmp also supports monitoring of intra-cardiac signals by transmitting signals to one of the unipolar precordial chest leads (leads V1-V6) of a Type CF, defibrillation-proof ECG monitor.

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.

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510(k) Summary

This 510(k) summary was prepared to provide an understanding of the basis for the determination of substantial equivalence in accordance with the requirements 21 CFR 807.92.

Submitters Name:	Atrility Medical, LLC 313 Price Place, Suite #13 Madison, WI 53705
Contact Person:	Matthew Knoespel, Regulatory Engineer Atrility Medical, LLC
Contact Phone:	Phone: 920-619-8737
Date Summary Prepared:	June 22, 2020
Device Trade Name:	AtriAmp
Common Name:	Passive interface cable to external pacemaker, epicardial pacing lead wire and cardiac monitor
Classification Name:	21 CFR 870.290 Patient transducer and electrode cable (including connector) Product Code: DSA, Class II
Predicate Devices:	K080621, Fastlock Pacing Wire Extension (Primary Predicate) K070926, Electrode/Extension Cables, Model series ATAR

Device Description

The AtriAmp acts as a connection hub for these three systems (external pacemaker, patient contacting external pacemaker lead wires and cardiac monitor) to provide a real-time, continuous atrial electrogram to the cardiac monitor while simultaneously allowing pacing of the atrium. The AtriAmp is a sterile, single patient use device.

Intended Use of the Device

The AtriAmp is a single-use device that is intended to connect an electrode/lead from a patient to a Type CF, defibrillation-proof ECG Monitor and/or an external pacemaker.

Summary of Technological Characteristics

The following table provides a side-by-side comparison of the AtriAmp to the predicate devices applied to support this pre-market notification.

Technical Characteristics Comparison				
Feature	**AtriAmp and Accessories Under Review**	**Fastlock Pacing Wire Extension Cable (Primary Predicate: K080621)**	**Electrode/Extension Cables, Model series ATAR Predicate: K070926**	**Equivalence Comments**
Product Code, Classification	DSA, 21 CFR 870.2900, Class II	DSA, 21 CFR 870.2900, Class II	IKD, 21 CFR 890.1175 Class II	Identical to primary predicate.

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Technical Characteristics Comparison				
Feature	**AtriAmp and Accessories Under Review**	**Fastlock Pacing Wire Extension Cable (Primary Predicate: K080621)**	**Electrode/Extension Cables, Model series ATAR Predicate: K070926**	**Equivalence Comments**
Indications for Use	The AtriAmp supports pacing by acting as an extension cable between an external pacemaker and cardiac pacing leads. The AtriAmp also supports monitoring of intra-cardiac signals by transmitting signals to one of the unipolar precordial chest leads (leads V1-V6) of a Type CF, defibrillation-proof ECG monitor.	Fastlock pacing wire extension cable with connectors is indicated for use as an electrical extension cable used to transmit signal from, or power or excitation signal to patient-connected electrodes.	Electrode/extension cable is intended to connect an electrode/lead from a patient or another cable to a diagnostic machine or an external pacemaker.	Equivalent The same as the predicate devices, the AtriAmp interfaces between an external pacemaker and patient applied intra-cardiac pacing lead wires. Equivalent to the secondary predicate, the AtriAmp interfaces the signal from the epicardial lead wires to a, defibrillation-proof ECG Monitor, one of the leads (V1 to V6) of an ECG monitor.
Duration of use	Anticipated to be less than 14 days	≤ 7 Days	≤ 7 Days	Similar
Single use, disposable	Yes	Yes	Yes	Same
Provided sterile	Yes	Yes	Yes	Same
Sterilization method	e-beam	ethylene oxide	ethylene oxide	Similar
Sterility Assurance Level (SAL)	$\leq 10^{-6}$	Unknown	Unknown	Acceptable for the intended use
Sterile barrier package	Flexible Double Pouch	Tyvek Flexible Barrier	Tyvek Flexible Barrier	Similar
Biocompatibility evaluation	Cytotoxicity, Irritation, Sensitization	Unknown	Unknown	Similar

Non-clinical Performance Tests

To establish the technical equivalency of the AtriAmp with accessories, evaluations were conducted to confirm compliance with performance requirements, including:

Test	**Test Method Summary**	**Result**
ANSI/AAMI EC53:2013 compliance	The AtriAmp complies with applicable requirements of EC53:2013 and performs the same as the predicate for Subclause 5.3.2 Cable and leadwire noise.	Pass
ANSUI/AAMI ES 60601-1 and IEC 60601-2-31 compliance	The AtriAmp with accessory external pacemaker interface cables complies with applicable requirements of ANSI/AAMI ES60601-1:2005 & A1:2012 and IEC 60601-2-31:2011.	Pass

Test	Test Method Summary	Result
ES60601-1 Subclause 8.5.2.3	In support of 21 CFR Part 898 compliance, the AtriAmp complies with ES60601-1 Subclause 8.5.2.3 Patient leads or patient cables.	Pass
Sterility	Sterilization of the subject device was validated according to ISO 11137-1:2006(R)2015 & A1:2013 & A2:2018, demonstrating the device is provided with a minimum sterility assumed level (SAL) of 10^{-6}.	Pass
Sterile barrier integrity	The sterile barrier package is a flexible pouch. The methods applied to evaluate the sterile barrier package integrity included post terminal sterilization simulated distribution, seal peel and bubble emission testing.	Pass
Biocompatibility	The ISO 10993-5:2009 and ISO 10993-10:2020 test methods were applied, with passing results: for Cytotoxicity, Sensitization, Irritation.	Pass
Shelf life two (2) years	Confirmation of device functional performance and sterile barrier pouch integrity (seal peel per ASTM F88 and bubble leak per ASTM F2096) with accelerated aging and simulated distribution per ASTM 4169-16 and bubble leak (ASTM F2096).	Pass
Duration of use	Operation use was evaluated to verify use for up to 14 days.	Pass

Clinical data are not needed.

Conclusion

The AtriAmp with accessories meet performance requirements equivalent to the predicate device. The intended use and technology of the AtriAmp with accessories is the same as the predicate device.