October 16, 2020

Accuro Technologies Inc.
Michael Dolphin
Chief Technology Officer
201-2067 Cadboro Bay Rd
Victoria, BC V8R 5G4
Canada

Re: K201816
Trade/Device Name: Arthrotap
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: October 2, 2020
Received: October 2, 2020

Dear Michael Dolphin:

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,

For CAPT Alan Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201816

Device Name
ARTHROTAP

Indications for Use *(Describe)*
The ARTHROTAP is intended for use by healthcare professionals for general purpose fluid aspiration/injection.

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

K201816

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

Accuro Technologies, Inc.
201-2067 Cadboro Bay Rd.
Victoria, BC CANADA V8R 5G4
Phone: 250-940-0015

Contact Person: Michael Dolphin, CTO
Phone: 604-970-2714
Email: mdolphin@accurotechnology.com

Date Prepared: October 8, 2020

II. DEVICE

Name of Device:	ARTHROTAP
Regulation Name:	Syringe, Piston
Regulation number:	21 CFR §880.5860
Regulatory Class:	Class II
Product Code:	FMF

III. PREDICATE DEVICE

Predicate Manufacturer:	Anutra Medical, Inc.
Predicate Trade Name:	Anutra Feedback Aspiration Syringe
Predicate 510(k):	K143757

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The ARTHROTAP is a fluid switching medical device consisting of a clear plastic barrel body, a sliding rod, two 6% female Luer lock connections, and one 6% male Luer lock connection. The

internal surface of the ARTHROTAP device barrel body is lubricated with polydimethylsiloxane (silicone).

The ARTHROTAP is single-use only, non-pyrogenic, and sterilized by electron beam irradiation.

V. INTENDED USE

The ARTHROTAP is intended for use by healthcare professionals for general purpose fluid aspiration/injection.

VI. PREDICATE DEVICE COMPARISON – TECHNOLOGICAL CHARACTERISTICS

Equivalency of technical characteristics is demonstrated through a direct comparison of the ARTHROTAP and the predicate device listed in the table below.

Technical Characteristic	**Subject Device: ARTHROTAP**	**Predicate Device: ANUTRA Feedback Aspiration Syringe (K143757)**	**Differences and impact on Safety and Efficacy**
Indications for Use	Intended for use by healthcare professionals for general purpose fluid aspiration/injection.	Intended for use by healthcare professionals for general purpose fluid aspiration/injection.	No difference.
Barrel (body)	Yes (clear Tritan Copolyester)	Yes (clear Polypropylene copolymer)	No new safety concerns as ARTHROTAP passed all biocompatibility tests.
Rod	Yes (sliding; white polycarbonate)	Yes (plunging; clear Polypropylene copolymer)	No new safety concerns as ARTHROTAP passed all biocompatibility tests.
Sealing Mechanism	O-rings (silicone)	Plunger (silicone)	No difference.
Luer Configuration	Luer Lock	Luer Lock	No difference.
Lubrication	Polydimethylsiloxane (silicone)	Polydimethylsiloxane (silicone)	No difference.
Sterilization Method	Irradiation (e-beam)	Irradiation (Gamma)	Both e-beam and gamma are established “Category A” sterilization methods which use irradiation. There are no new concerns for safety or efficacy.

External connections	Has 3 Luer connectors. Intended to connect to two syringes and a single needle	Has 1 Luer connector. Intended to connect to a single needle	Additional connections (to syringes) does not pose new concerns as the ARTHROTAP is intended to be connected to syringes, which have the same safety and efficacy concerns as the ANUTRA syringe. Both devices are intended to be connected to a needle, which has no new concerns.
Operation / Actuation method	Pressing the sliding rod horizontally to open and close fluid paths by means of moving sliding seals within the device.	Pressing or pulling the sliding rod vertically to move the sliding seal within the device to compress or expand hollow space inside cylinder.	The method of operation for both devices involves moving sliding seals within the device by means of pressing (or pulling) on a sliding rod. There are no new safety or efficacy concerns, as the method of sealing is the same (sliding seals), and the method of operation is very similar.
Calibration	The ARTHROTAP is a pass-through device, is not calibrated for volume, and does not have graduated markings.	Is calibrated, and has graduated markings	There are no new safety or efficacy concerns with the ARTHROTAP as the device is a pass-through device and does not require calibration or graduated markings. (For procedures where graduated markings are required, users can attach a calibrated syringe to the ARTHROTAP).

The predicate device is a piston syringe intended for general purpose fluid aspiration and injection. The ARTHROTAP is a fluid switching device intended for general purpose aspiration and injection. The intended use for the ARTHROTAP is the same as its predicate device, the ANUTRA Feedback Aspiration Syringe (K143757).

Barrel (body)

Both the ARTHROTAP and ANUTRA Feedback Aspiration Syringe have clear bodies made from plastic. The ARTHROTAP does not hold or measure quantities of fluid, but allows fluid to be passed through it; whereas the ANUTRA Feedback Aspiration Syringe can hold a 5 mL nominal fluid volume, indicated by graduation marks printed on the outside of the barrel.

Luer Configuration

Both the ARTHROTAP and ANUTRA Feedback Aspiration Syringe have male Luer locks intended to connect to an external needle (not provided). Additionally, the ARTHROTAP has two female Luer locks intended to connect with external syringes (not provided).

Nominal Fluid Volume

The nominal fluid volume for one fluid pathway of the ARTHROTAP is 250 µLor 0.25 mL (it is a pass-through device and not intended to hold fluids). The ANUTRA Feedback Aspiration Syringe has a nominal fluid volume of 5 mL.

Lubrication

The internal surface of both the ARTHROTAP and ANUTRA Feedback Aspiration Syringe is lubricated with a polydimethylsiloxane (silicone).

Plunger Rod & Plunger

Both the ARTHROTAP and the ANUTRA Feedback Aspiration Syringe device have a plastic rod to operate the device. The ARTHROTAP has a sliding rod and the ANUTRA Feedback Aspiration Syringe has a plunging rod. Both devices have a rod which attach with snap-fit retention features. The ARTHROTAP and ANUTRA Feedback Aspiration Syringe rods both contain features which provide tactile feedback when the plunger is advanced or retracted.

Sterilization Method

Both the ARTHROTAP and the ANUTRA Feedback Aspiration Syringe are sterilized using irradiation. ARTHROTAP is sterilized using electron beam irradiation; the ANUTRA Feedback Aspiration Syringe is sterilized using gamma irradiation.

External connections

Both the ARTHROTAP and the ANUTRA Feedback Aspiration Syringe have external Luer connections. The ARTHROTAP has two female Luers and one male Luer; the ANUTRA Feedback Aspiration Syringe has one male Luer.

Operation / Actuation method

Both the ARTHROTAP and the ANUTRA Feedback Aspiration Syringe are operated by means of a sliding rod with internal sealing mechanism. The ARTHROTAP's rod is operated horizontally by means of pressing either side; the ANUTRA Feedback Aspiration Syringe's rod is operated vertically by means of pushing and pulling.

Calibration

The ARTHROTAP does not have a calibration feature as it is a pass-through device; the ANUTRA Feedback Aspiration Syringe has graduated marks for calibration.

Materials

The ARTHROTAP is constructed of the following materials:

- Barrel (body): Tritan Copolyester
- Sliding Rod, End Cap, End Covers: Polycarbonate
- O-rings: Dow Corning QP1-50 Silicone
- Lubricant: Polydimethylsiloxane (silicone)

The ARTHROTAP and ANUTRA Feedback Aspiration Syringe have both been tested and found to meet the biological requirements outlined in ISO 10993-1 (biocompatibility).

Predicate Device Comparison – Performance Characteristics

The performance data supplied with this submission demonstrates that the ARTHROTAP meets the specified requirements and is substantially equivalent to the predicate device.

The predicate device (ANUTRA Feedback Aspiration Syringe) provided an overview of testing completed in the 510(k) Summary (K143757). The following tests were performed to demonstrate safety and effectiveness and are substantially equivalent to the tests performed on the ANUTRA Feedback Aspiration Syringe.

<u>Tests performed on Subject Device:</u>

ISO 7886-1:2017 (Sterile hypodermic syringes for single use)

- Section 5 (General)
- Section 6.2 (Limits for Acidity or Alkalinity)
- Section 6.3 (Limits for Extractable Metals)
- Section 7 (Lubricant)
- *Section 8 (Tolerance on graduated capacity) – N/A, no graduated capacity on ARTHROTAP*
- *Section 9 (Graduated scale)- N/A, no graduated scale on ARTHROTAP*
- Section 10 (Barrel)
- Section 11 (Piston/plunger assembly); Annex B
- Section 12 (Nozzle)
- *Section 13.1 (Dead Space) – N/A*
- Section 13.2 (Freedom from air and liquid leakage); Annex B & Annex D
- Section 13.3 (Force to operate piston); Annex E
- Section 13.4 Fit of plunger in barrel
- Section 14 (Packaging)
- Section 15 (Labeling)

ISO 80369-7:2016 (Small-bore connectors), using test methods provided in [section] of ISO 80369-20:2015 (Common Test Methods)

- Section 5 (Dimensional Requirements)
- Section 6.1 (Liquid leakage from fitting assembly under pressure), [Annex C]

- Section 6.2 (Sub-atmospheric Air leakage into fitting assembly during aspiration), [Annex D]
- Section 6.3 (Stress Cracking), [Annex E]
- Section 6.4 (Resistance to separation from axial load), [Annex F]
- Section 6.5 (Resistance to separation from unscrewing), [Annex G]
- Section 6.6 (Resistance to overriding), [Annex H]

Sterile Barrier Packaging Testing

- ASTM F1980-16 Environmental Conditioning
- ASTM D4169-16 Distribution Simulation
- Label Inspection for overall adhesion and legibility (Pass/Fail)
- ASTM F2096-11 Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Leak).
- ASTM F88 / F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials.

ISO 10993-1:2009 (Biocompatibility)

- Section 6.2.2.2 Cytotoxicity by Elution Test (Cytotoxicity)
- Section 6.2.2.3 Maximization Test for Delayed Hypersensivity (Sensitization)
- Section 6.2.2.4 Intracutaneous Reactivity (Irritation or Intracutaneous Reactivity)
- Section 6.2.2.5 Acute Systemic Toxicity (Systemic Toxicity (Acute))
- Section 6.2.2.9 Evaluation of Hemocompatibility: Interaction with Blood (Hemocompatibility/Hemolysis)
- ISO 10993-12 & USP <151>(Pyrogenicity)
- USP 40 <85> Bacterial Endotoxin (LAL)
- USP <788> Particulate Matter In Injections

(Sterilization)

- Bioburden (ANSI/AAMI/ISO 11737-1:2006)
- Bioburden Validation (ANSI/AAMI/ISO 11737-1:2006)
- VD Maximum Dose (ANSI/AAMI/ISO TIR13004:2013)
- Sterility Verification (ANSI/AAMI/ISO 11737-2:2009/(R) 2014)
- Dose Mapping (ISO 11137-1:2006)
- Device Sterilization (ANSI/AAMI/ISO 11737-2:2009/(R) 2014)

Discussion of Non-Clinical Testing

Performance testing of ARTHROTAP was conducted and evaluated in accordance with ISO 7886-1 “Sterile hypodermic syringes for single use – Part 1: Syringes for manual use”, and according to ISO 80369-7 “Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications”, using test methods provided in ISO 80369-20 “Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common Test Methods”. Demonstration of meeting these standards was

considered important to demonstrate safety and efficacy of ARTHRTOAP and for demonstrating substantial equivalence to the predicate device, particularly in operation of the plunger rod and the ability of the device to hold a seal.

Package testing was conducted in accordance with ASTM F1980-16, ASTM D4169-16, ASTM F2096-11, ASTM F88 / F88M-15, meeting a level of safety demonstrated by the predicate device.

Biological specifications were determined in adherence to guidelines for the contact classification of: External communicating device, Blood path indirect, limited duration (< 24 hr). Biocompatibility testing was conducted in accordance with the FDA guidance “Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part1: Evaluation and testing within a risk management process””, June 16, 2016, and ISO 10993-1 “Biological evaluation of medical devices – Part1: Evaluation and testing within a risk management process”. The battery of testing included all tests conducted on the predicate, plus additional testing for Pyrogenicity and LAL, demonstrating safety of the device substantially equivalent or better than the predicate device.

Sterilization testing, including testing for Bioburden, Maximum Dose and Dose mapping, was conducted in accordance with ISO 11737-1, ISO 11737-2, ISO 11137-1, and ISO TIR13004. Sterilization testing is not listed for the predicate device, however, these tests demonstrated safety of ARTHROTAP for purposes of sterility.

Conclusion

Test results demonstrated that the ARTHROTAP is as safe, as effective, and performs as well as or better than the legally marketed predicate device (ANUTRA Feedback Aspiration Syringe). Based on comparisons of the device’s intended use, technology and performance characteristics, the ARTHROTAP is substantially equivalent to the indicated predicate device. Any differences between the ARTHROTAP and the ANUTRA Feedback Aspiration Syringe have no significant influence on safety or effectiveness.