July 25, 2023

Elcam Medical ACAL
% Shoshana Friedman
Senior Regulatory Consultant
ProMedoss Inc.
3521 Hatwynn Rd
Charlotte, North Carolina 28269

Re: K231900
Trade/Device Name: A-TAP
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: June 28, 2023
Received: June 28, 2023

Dear Shoshana Friedman:

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,

CAPT Alan M. 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)*
K231900

Device Name
A-TAP

Indications for Use *(Describe)*
The A-TAP 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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SPECIAL 510(K) SUMMARY
A-TAP™
510(k) Number K231900

1. SUBMITTER

Applicant's Name:
Elcam Medical ACAL
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Phone: (704) 430-8695
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2. DATE PREPARED

July 21, 2023

3. DEVICE

Device Trade Name:	A-TAP
Classification Name:	Syringe, Piston
Product Code:	FMF
Regulation No:	21 CFR §880.5860
Regulatory Class:	Class II

4. PREDICATE DEVICE

Predicate Trade Name: Arthrotap
Predicate 510(k) No.: K201816

5. DEVICE DESCRIPTION

The A-TAP device 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 device barrel body is lubricated with polydimethylsiloxane (silicone).
The A-TAP is a single-use only, disposable, non-pyrogenic and sterilized by Gamma irradiation.

6. REASON FOR SUBMISSION

The original Arthrotap device (now named A-TAP) was designed by Accuro Technologies and was cleared on October 16, 2020, under K201816.
Elcam Medical acquired the Arthrotap device from Accuro Technologies and Accuro Technologies transferred the ownership of the 510(k) number K201816 for the Arthrotap to Elcam Medical. As a result of Elcam Medical becoming the legal manufacturer of the device, several modifications were implemented, as presented in this Special 510(k) submission: materials change, irradiation method & packaging material and minor geometric design modifications.

7. INDICATIONS FOR USE

The A-TAP is intended for use by healthcare professionals for general purpose fluid aspiration/injection.

8. SUBSTANTIAL EQUIVALENCE

Equivalency of device and its predicate is demonstrated in Table 1 below through a direct comparison of the A-TAP and the predicate device (Arthrotap).

Table 1: Comparison Table

Characteristics	***Subject Device*** **A-TAP™ K231900**	***Predicate Device*** **Arthrotap K201816**	**Comparison Description and Analysis**
Indications for Use	The A-TAP is intended for use by healthcare professionals for general purpose fluid aspiration/injection.	The Arthrotap is intended for use by healthcare professionals for general purpose fluid aspiration/injection.	Substantially equivalent.
Barrel (body)	Clear Tritan	Clear Tritan	Same chemical family. Biocompatibility testing was performed for this material change to demonstrate substantial equivalence (see section 9 below).
Rod	Polycarbonate with white colorant	Polycarbonate with white colorant	Same chemical family. Biocompatibility testing was performed for this material change to demonstrate substantial equivalence (see section 9 below).
Sealing Mechanism	O-rings	O-rings	Similar sealing mechanism.

Characteristics	*Subject Device* A-TAP™ K231900	*Predicate Device* Arthrotap K201816	Comparison Description and Analysis
			Performance testing was performed to demonstrate substantial equivalency (see section 9 below).
Luer Configuration	Luer Lock	Luer Lock	Substantially equivalent.
Lubrication	Polydimethylsiloxane (silicone)	Polydimethylsiloxane (silicone)	Same chemical family. Biocompatibility and performance testing were performed for this material change to demonstrate substantial equivalence (see section 9 below)).
Sterilization Method	Irradiation (Gamma)	Irradiation (e-beam)	Similar. Both irradiation sterilization methods are Established Category A[1].
Packaging	Blister (as cleared under K190489)	Pouch	Sterilization, shelf-life and packaging integrity testing were performed for this change to demonstrate substantial equivalence (see section 9 below).
External Connections	3 Luer connectors Intended to connect to two syringes and a single needle	3 Luer connectors Intended to connect to two syringes and a single needle	Substantially equivalent
Operation /Actuation Method	Pressing the sliding rod horizontally to open and close fluid paths by means of moving sliding seals within the device.	Pressing the sliding rod horizontally to open and close fluid paths by means of moving sliding seals within the device.	Substantially equivalent
Calibration	The A-TAP is a pass-through device, is not calibrated for volume, and does not have graduated markings.	The Arthrotap is a pass-through device, is not calibrated for volume, and does not have graduated markings.	Substantially equivalent

The above comparison table demonstrates that Elcam's modified A-TAP is substantial equivalent to the predicate device (Arthrotap).
The raw materials change (all within the same chemical family), the change in irradiation method, and consequently, packaging change as well as the minor geometric design modifications do not alter neither the basic design nor the operation mechanism of the device, as supported by the results of the verification and validation tests.
It was, therefore, our conclusion that the A-TAP with the modifications requested in this submission is substantially equivalent to the market-cleared Arthrotap (cleared under K201816), without raising any new safety and/or effectiveness concerns.

[1] Per FDA guidance "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile" issued on January 21, 2016

9. PERFORMANCE DATA

Elcam's A-TAP successfully passed all the tests listed in Table 2 below.

Table 2: Performance Tests

Topic	Standard/Method
Biocompatibility	Cytotoxicity (ISO 10993-5)
	Irritation (ISO 10993-10)
	Sensitization (ISO 10993-10)
	Acute Systemic Toxicity (ISO 10993-11)
	Material-Mediated Pyrogenicity (ISO 10993-11/USP<151>)
	Hemolysis (ISO 10993-4)
Non-Clinical (Bench)	ISO 7886-1:2017, Sterile hypodermic syringes for single use - Part 1: Syringes for manual
	ISO 80369-7:2021, Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
	ISO 8536-10:2015, Infusion equipment for medical use — Part 10: Accessories for fluid lines for single use with pressure infusion equipment
Sterilization and Shelf Life	ANSI/AAMI/ISO 11737-1:2018, Sterilization of Health Care Products - Microbiological Methods - Part 1: Determination of a Population of Microorganisms on Products
	ANSI/AAMI/ISO 11737-2:2019, Sterilization of Medical Devices—Microbiological Methods—Part 2: Tests of Sterility Performed in the Definition, Validation and Maintenance of a Sterilization Process
	ANSI/AAMI/ISO TIR13004:2013 (R2016)/ ISO 13004:2022, Sterilization of Health Care Products - Radiation - Substantiation of Selected Sterilization Dose: Method VDmax SD
	ANSI/AAMI/ISO 11137-1:2006/(R)2015 [Including: Amendment 1 (2013) and Amendment 2 (2019)], Sterilization of Health Care Products - Radiation - Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices
	USP <85> Bacterial Endotoxin
	ASTM F 1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
Package Integrity	ASTM D 4169-16**,** Standard Practice for Performance Testing of Shipping Containers and Systems
	ASTM F2096-11 (Reapproved 2019), Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
	ASTM F88/F88M-21, Standard Test Method for Seal Strength of Flexible Barrier Materials
	USP <788 > Particulate Matter in Injections

The evaluation of Elcam's A-TAP by the tests detailed above demonstrated that the A-TAP device is as safe and as effective as the predicate device (Arthrotap).

10. CONCLUSION

The modifications discussed in this submission do not introduce new risks, do not affect the functionality of the device, and do not alter any of the labeling claims.
Therefore, it was concluded that Elcam's modified A-TAP is substantially equivalent to the Arthrotap previously cleared (K201816).