October 22, 2019

MonuMedical, LLC
℅ Cheryl Blake
Regulatory Affairs
27392 Capricho
Mission Viejo, California 92692

Re: K190539
Trade/Device Name: MonuMedical TurnSignal® Stopcocks and Manifolds
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FMG
Dated: September 19, 2019
Received: September 23, 2019

Dear Cheryl Blake:

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 Geeta Pamidimukkala
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190539

Device Name

MonuMedical TurnSignal® Stopcocks and Manifolds

Indications for Use *(Describe)*

MonuMedical TurnSignal® Stopcocks and Manifolds are indicated for fluid flow directional control and providing access port(s) for administration of solutions. Typical uses include pressure monitoring, intravenous fluid administration and transfusion.

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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K190539

510(k) Summary of Substantial Equivalence

MonuMedical TurnSignal® Stopcocks and Manifolds

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21CFR 807.92, MonuMedical, LLC. is hereby submitting the 510(k) Summary of Substantial Equivalence for 510(k) prepared October 21, 2019.

A. Submitter

MonuMedical, LLC
3017 Douglas Boulevard, Suite 300
Roseville, CA 95661

Establishment Registration: Not yet Registered

Applicant Correspondent

Cheryl Blake
Regulatory Consultant
27392 Capricho
Mission Viejo, CA 92692
cherylblake@cox.net
949-285-3517

B. Device Name

Proprietary Name: MonuMedical TurnSignal® Stopcocks and Manifolds

Part Number	Description
S133000	3-Port 3-Way Stopcock sterile
S134000	3-Port 4-Way Stopcock sterile
S434012	4 Stopcock Manifold (3-Port 4-Way Stopcock) Sterile
B133000	3-Port 3-Way Stopcock Bulk non sterile
B134000	3-Port 4-Way Stopcock Bulk non sterile
B434012	4 Stopcock Manifold (3-Port 4-Way Stopcock) Bulk non sterile

Common Name:	Stopcocks and manifolds
Classification Name:	Intravascular Administration Set
Regulation Number:	880.5440
Product Code:	FMG
Regulatory Class:	II
Panel:	General Hospital

C. Predicate Device(s)

Device Name:	Elcam Medical ACAL Stopcocks and Manifolds
Company Name:	Elcam Medical ACAL Kibbutz BarAm, Merom HaGalil 1386000 Israel
510(k):	K022895

D. Device Description

MonuMedical TurnSignal® Stopcocks and Manifolds are composed of a stopcock with three port three way and or three port four way body and a handle. Male connectors also include a nut for locking over the female connector or another component. A small amount of lubricant is applied between the stopcock body and handle. The manifolds contain a Halkey Roberts Swabable Port on each stopcock. MonuMedical Stopcocks will be available in a wide variety of configuration for use according to a particular situation and the clinician's preference. Duration of use should not exceed 24 hours and 7 activations of the swabable ports. The devices are provided sterile and non-sterile.

E. Intended Use / Indications for Use

MonuMedical TurnSignal® Stopcocks and Manifolds are indicated for fluid flow directional control and providing access port(s) for administration of solutions. Typical uses include pressure monitoring, intravenous fluid administration and transfusion.

F. Substantial Equivalence

The MonuMedical TurnSignal® Stopcocks and Manifolds are substantially equivalent to the Elcam Stopcocks and manifolds cleared under 510K K022895.
The MonuMedical TurnSignal® Stopcocks and Manifolds are the same indications for used, principle of operation, shape, sterilization method as the predicate device.

Feature	TurnSignal Stopcocks and Manifolds	Predicate, Elcam Stopcocks and Manifolds K022895	Comparison
Indication for Use	MonuMedical TurnSignal® Stopcocks and Manifolds are indicated for fluid flow directional control and providing access port(s) for administration of solutions. Typical uses include pressure monitoring, intravenous fluid administration and transfusion.	Elcam Stopcocks and Manifolds are indicated for fluid flow directional control and for providing access port(s) for administration of solutions. Typical uses include pressure monitoring, intravenous fluid administration and transfusion.	Same indication- Difference is regarding subject device name
Design similarities	Stopcocks have a body and core – the design is similar in clarity, BPA free. Female and male connectors. A small amount of lubricate is applied between stopcock body and handle/core. Available in variety of	Stopcocks have a body and core – the design is similar in clarity, BPA free. Female and male connectors. A small amount of lubricate is applied between stopcock body and handle/core. Available in variety of	Same

	configurations. Sam shape and use luer fittings. Vented luer caps. Available as single stopcocks and manifolds.	configurations. Sam shape and use luer fittings. Vented luer caps. Available as single stopcocks and manifolds	
Device configurations included	3 way 3 port 3 way 4 port 3 way 4 stopcock manifold with swabable ports	3 way 3 port 3 way 4 port 3 way 4 stopcock manifold with swabable ports	Same
Design differences	TurnSignal indicator allows easy identification of which ports are on/off	No indicator to user – handle only	Ease of use of TurnSignal stopcock with flow indicator
Materials	HDPE Core, Tritan Body	HDPE Core, Tritan Body	Same
Packaging	3 mil poly/poly pouch	Tyvek or paper/polyethylene pouch	Similar – both are industry standard and appropriate for radiation sterilized product.
Sterilization	Gamma, provided sterile and bulk non-sterile	Gamma	Same Sterilization method
Shelf Life	1 year	Unknown – some packaging indicates 1 year	Similar – shelf life testing in accordance with ISO 11607.
Single Use	yes	yes	Same
Biocompatibility	ISO 10993-1	ISO 10993-1	Same
Microbial Ingress	24 hours	Unknown	Subject device completed microbial ingress testing

G. Non-clinical Performance Testing

Non-clinical bench testing demonstrated the MonuMedical TurnSignal® Stopcocks and Manifolds are substantially equivalent to the predicate with regard to intended use, materials, technology, and performance. Design verification testing, demonstrates performance related to product label claims.

- Microbial Ingress challenge was completed to support duration of use of 24 hours.
- ISO 16775 Packaging for terminally sterilized medical devices
- ANSI AAMI ST67 Sterilization of health care products-Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled 'sterile'
- ASTM D4169 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM D4332 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
- ISO 11137-1 Sterilization of Health Care Products Part 1
- ISO 11137-2 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
- ASTM F88 Standard Test Method for Seal Strength of Flexible Barrier Materials
  - Pull seal testing completed
- ASTM F1886 Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection
  - Visual inspection per standard
- ASTM 1980 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
  - Aging of devices completed prior to testing
- ASTM F2096 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble test)
  - Bubble testing of packaging
- ISO 11607 Packaging for terminally sterilized medical devices
- ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing
  - Testing of cytotoxicity, intracutaneous, sensitization, acute systemic toxicity, hemolysis, and materials mediated pyrogen were completed.
- ISO 80369-7 Small-bore connectors for liquids and gases in healthcare applications
  - Falling drop Positive pressure liquid leakage testing
  - Sub atmospheric pressure Air Leakage

        - Stress Cracking
        - Resistance to Separation from Axial Load
        - Resistance to Separation from Unscrewing
        - Resistance to overriding
    - ISO 80369-20 Thread gauge testing
    - Leak testing
    - ISO 594-1-go/no go taper block 6% taper

H. Conclusion

Through the performance testing completed Monumedical has demonstrated that the MonuMedical TurnSignal® Stopcocks and Manifolds are substantial equivalent to the predicate device Elcam Stopcocks and manifolds cleared under 510K K022895.