July 21, 2023

M/s Romsons International
Kishore Khanna
Partner
Unit-II, 9, Noida Special Economic Zone, Noida Dadri Road,
Phase - II Noida, Gautam Buddha N
Noida, Uttar Pradesh 201305
India

Re: K223499
Trade/Device Name: Three Way Stop Cock
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FMG
Dated: June 21, 2023
Received: June 21, 2023

Dear Kishore Khanna:

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,

David Wolloscheck

David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
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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)*
K223499

Device Name
Three Way Stop Cock

Indications for Use *(Describe)*
3-way stopcocks are indicated for venous or arterial use, as IV add-on devices used for simultaneous infusions, intermittent drug injections, for central venous pressure measurements, and as arterial add-on devices used for invasive pressure measurements, flushing with normal saline.

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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K223499 – 510 (k) Summary

Device Name- Three Way Stop Cock

5.1 Submitter Information [21 CFR 807.92(a) (1)]

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5.2 Date Prepared

July 21, 2023

5.3 Subject Device [21 CFR 807.92(a) (2)]

Trade Name:	Three Way Stop Cock
Common Name:	IV Set Stopcock
Regulation Name:	Intravascular Administrator Set
Regulation Number:	21 CFR 880.5440
Product Code:	FMG
Device Class:	Class II
Classification Panel:	General Hospital

5.4 Predicate Device [21 CFR 807.92(a) (3)]

K141254; Elcam Medical Stopcocks and manifolds with Safe2 Rotator by Elcam Medical ACAL, Israel.

5.5 Device Description [21 CFR 807.92(a) (4)]

Three Way Stop cock is composed of a Body, Rotating Handle, Luer Ports – with 2 female luer lock & 1 male luer lock with Rotating Nut. Compatible with 6% Luer combination devices. Transparent, lipid resistant body, provides easy visualization, and indicates fluid path.

The device is designed and tested as per its device specific guidance; "Intravascular Administration Sets Premarket Notification Submissions [510(k)]".

Figure 5.1: Three Way Stop Cock

Product Code: GS-3164
Device Name: Three Way Stop Cock

3- Way Stop Cock is used for pressure infusion, for selective running of one or two paths intravenous lines & for measurement & also for monitoring of central venous pressure. 3- Way Stop Cock lipid-resistant is for infusing lipid-fluids & other intravenous fluids. Maximum use duration of the device is not beyond 5 days.

User Profile/Population: Adult & Pediatric

5.6 Indications for Use [21 CFR 807.92(a) (5)]

3-way stopcocks are indicated for venous or arterial use, as IV add-on devices used for simultaneous infusions, intermittent drug injections, for central venous pressure measurements, and as arterial add-on devices used for invasive pressure measurements, flushing with normal saline.

5.7 Comparison of the technological characteristics with the predicate device [21 CFR 807.92(a) (6)]

Traditional 510(k) Premarket Submission.
Three Way Stop Cock
The comparison chart below provides evidence to facilitate the substantial equivalence determination between Three Way Stop Cock and the predicate device (K141254) with respect to the Indications For use, technological characteristics and principles of operation.

Table 5.1. Comparison of Characteristics

Comparison parameters	**Three Way Stop Cock by M/s Romsons International K223499**	**Elcam Medical Stopcocks and manifolds with Safe2 Rotator by Elcam Medical ACAL K141254**	**Substantial Equivalence Discussion**
Indications for Use	3-way stopcocks are indicated for venous or arterial use, as IV add-on devices used for simultaneous infusions, intermittent drug injections, for central venous pressure measurements, and as arterial add-on devices used for invasive pressure measurements, flushing with normal saline.	Elcam Medical Stopcocks and manifolds with Safe2 Rotator 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; even though the statement is not exactly the same, the intended use is the same.
Product Code	FMG	FMG	Same
Design			Similar, additional Luer Lock Cap for safety purpose given to Three Way Stop Cock by M/s Romsons International Performance testing (e.g., ISO 80369-7) was perform to demonstrate substantial equivalence.
Material of Construction	Body made up of Poly carbonate/Polysulfone it is lipid resistance material and rotating handle is made up of poly ethylene	Body made up of Polycarbonate/ Polysulfone it is lipid resistance material and rotating handle is made up of poly ethylene	Similar; biocompatibility testing was performed to ensure that the subject device is as safe and effective as the predicate.
Type of configuration	2- Female Luer Lock & 1 – Male Luer Lock	2- Female Luer Lock & 1 – Male Luer Lock	Same
6% Male Luer Lock Fitting	Proper lock fitting with gauge as per ISO 80369-7:2021	Proper lock fitting with gauge as per ISO 594-2	Similar; the luer testing is performed per the updated ISO standard

Comparison parameters	Three Way Stop Cock by M/s Romsons International K223499	Elcam Medical Stopcocks and manifolds with Safe2 Rotator by Elcam Medical ACAL K141254	Substantial Equivalence Discussion
6% Female Luer Lock Fitting	Proper lock fitting with gauge as per ISO 80369-7:2021	Proper lock fitting with gauge as per ISO 594-1	Similar; the luer testing is performed per the updated ISO standard Similar
Colour of Main Body	Clear/ Transparent	Clear/ Transparent	Same
Colour of Rotating Handle	Blue	Blue	Same
Colour of Rotating Luer Lock Nut	Clear/ Transparent	Clear/ Transparent	Same
Arrow Indication on Rotating Handle	Yes	Yes	Same
Product Performance Specifications	**Meets:** ISO 8536-10, ISO 80369-7, ISO 80369-20, ISO 10555-1	**Meets:** ISO 8536-10, ISO 80369-7, ISO 80369-20, ISO 10555-1	Same
Flow rate	As Per ISO 10555-1	As per ISO 10555-1	Same
Blockage Test	Three Way Stop Cock Connector Connect with Syringe Luer and Passes Water	Water easily passes	Same
Leakage	No Leakage	No Leakage	Same
Biocompatibility	Complies all requirements of ISO 10993-1	Complies all requirements of ISO 10993-1	Same
Non-Toxic	Yes	Yes	Same
Non-Pyrogenic	Yes	Yes	Same
Single Use	Yes	Yes	Same
Sterile	Yes	Yes	Same
Sterilization Method	ETO	ETO	Same
Prescription Use	Yes (Rx Only)	Yes (Rx Only)	Same

Romsons Three Way Stop Cock has similar indications for use statement as the predicate device. The device has similar Design characteristics & same material of construction as the predicate device. Both devices have the same Product Performance Specifications. The results of the performance testing demonstrate substantial equivalence. The minor differences in the product does not affect the products safety and effectiveness.

5.8 Performance Data [21 CFR 807.92(b)]: Summary of non-clinical tests conducted for determination of substantial equivalence [21 CFR 807.92(b) (1)]

To verify that the Three Way Stop Cock meet the design requirements, testing was conducted in accordance with "Intravascular Administration Sets Premarket Notification Submissions [510(k)]" guidance, ASTM and ISO standards. Risk analysis was carried out in accordance with established in house acceptance criteria based on ISO 14971:2019. Non-clinical performance tests conducted on Three Way Stop Cock are listed in table 5.2.

Biocompatibility tests were performed according to ISO 10993-1:2018 recognized consensus standard and additional parts for each test in conjunction with most current FDA's Guidance for Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".
With respect to raw materials of the subject device, manufacturing agents and processing, no new risks are being introduced. All materials in contact with body tissue or fluids meet ISO 10993, Part 1 "Biological Evaluation of Medical Devices" under the following classification: External Communicating Device Tissue which comes in contact with blood path indirect, prolonged duration (>24 h to 30d).

All test that are required by ISO 10993-1 were performed for the respective endpoints including in vitro cytotoxicity, intracutaneous reactivity, skin sensitization, hemolysis, acute systemic toxicity and repeated dose 28 days toxicity. The biocompatibility tests conducted with respect to these endpoints are listed in table 5.3.
The results of biocompatibility showed that the finished products comply with the requirements of ISO 10993-1 serial standards applicable for Three Way Stop Cock.

The results of the performance testing demonstrate fulfilment of requirements as per device specific guidance "Intravascular Administration Sets Premarket Notification Submissions [510(k)]" guidance as well as substantial equivalence with predicate. The minor differences in the product does not affect the products safety and efficacy.

Table 5.2. Non-Clinical Performance Tests

Testing Standard	Purpose of the Test
ISO 8536-10:2015	Infusion equipment for medical use
ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications
ISO 80369-20:2021	Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods
ISO 10993-4:2017	Selection of tests for interactions with blood (Hemolysis Test)
ISO 10993-5:2009	Tests for in vitro cytotoxicity

ISO 10993-7:2008	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
ISO 10993-10:2021	Biological evaluation of medical devices — Part 10: Tests for skin sensitization
ISO 10993-10:2021	Intracutaneous Reactivity Test
ISO 10993-11:2017	Tests for systemic toxicity
USP 2018, Vol.41 ISO 10993-11:2017	Material Mediated Pyrogenicity Test
ISO 11135:2014	Sterilization of health-care products — Ethylene oxide
ISO 11607-1:2019 ISO 11607-2:2019	Packaging for terminally sterilized medical devices
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ISO 10555-1:2013	Intravascular catheters - Sterile and single-use intravascular catheters - Part 1: General requirements
ASTM F 1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
USP <788>	Particle matter test

Table 5.3. Biocompatibility Tests

Testing Standard	**Purpose of the Test**
ISO 10993-4:2017	Selection of tests for interactions with blood (Hemolysis Test)
ISO 10993-5:2009	Tests for in vitro Cytotoxicity
ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene Oxide Sterilization residuals
ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for Skin Sensitization
ISO 10993-10:2021	Intracutaneous Reactivity Test
ISO 10993-11:2017	Tests for Systemic Toxicity
ISO 10993-11:2017	Repeated dose 28-days toxicity test
ISO 10993-11:2017	Material Mediated Pyrogenicity Test

5.9 Summary of clinical tests conducted for determination of substantial equivalence or of clinical information [21 CFR 807.92(b) (2)]

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device.

5.10 Statement of Substantial Equivalence [21 CFR 807.92(b) (3)]

Romsons Three Way Stop Cock has the similar Indications For use as the predicate device and the device do not raise additional questions of safety and effectiveness.

The conclusion drawn from the non-clinical test demonstrates that Romsons Three Way Stop Cock is as safe and effective and performs similar than the predicate device. Therefore, the subject device is substantially equivalent to the predicate device.