May 14, 2018

MYCO Medical Supplies, Inc.
% E. J. Smith
Smith Associates
1468 Harwell Ave.
Crofton, Maryland 21114

Re: K173279
Trade/Device Name: RELI® Safety Blood Collection Tube Holder and RELI® Blood Collection Tube Holder
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: April 10, 2018
Received: April 13, 2018

Dear E. J. Smith:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*

K173279

Device Name

RELI® Safety Blood Collection Tube Holder and RELI® Blood Collection Tube Holder

Indications for Use *(Describe)*

The RELI® Safety Blood Collection Tube Holder and the RELI® Blood Collection Tube Holder are intended to enable withdrawal of blood samples from a patient.

The RELI® Safety Blood Collection Tube Holder is designed to prevent accidental needle stick injuries.

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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K173279

510k Summary

SPONSOR

Company Name:	MYCO Medical
Company Address:	2015 Production Drive Apex, NC 27539
Telephone:	919-460-2535
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Contact Person:	Sanjiv Kumar
Title:	President & CEO
Email	skumar@mycomedical.com
Summary Preparation Date:	September 29, 2017

DEVICE NAME

Trade Name:	RELI® Safety Blood Collection Tube Holder and RELI® Blood Collection Tube Holder
Common/Usual Name:	Evacuated Blood Collection Tube Holder
Classification Name:	Needle, Hypodermic, Single Lumen
Regulation Number:	21 CFR 880.5570
Product Code:	FMI
Device Class:	II
Classification Panel:	General Hospital

PREDICATE DEVICE

Trade name:	VACUETTE QUICKSHIELD with SNAPPY Tube Holder
510k:	K113505
Common /Usual Name:	Evacuated Blood Collection Tube Holder
Regulation Number:	21 CFR 880.5570
Regulation Name:	Needle, Hypodermic, Single Lumen
Regulatory Class:	II
Product Code:	FMI
Classification Panel:	General Hospital

DEVICE DESCRIPTION

The RELI® Safety Blood Collection Tube Holder and RELI® Blood Collection Tube Holder are intended to be used in combination with conventional multiple sample blood collection needles (up to 1 ½" in length) and vacutainers for safe handling and disposal immediately following routine venipuncture procedures.

The Safety Blood Collection Tube Holder is designed with a user activated safety shield to cover the needle immediately following venipuncture procedure to help prevent needle stick injuries and safely dispose of the device in compliance with OSHA requirements.

The safety shield can be activated by gently pressing the shield toward the needle in one of two ways without the need for user to approach the sharp end:

1) Press shield toward exposed needle on a stable surface – or –
2) With thumb behind the shield, press shield onto exposed needle.

An audible click is heard when the safety shield has been properly activated and the Safety Blood Collection Tube Holder with enclosed needle is safe to discard.

The Safety Blood Collection Tube Holder is clear with safety shield available in clear, blue, or orange color options. The Blood Collection Tube Holder is clear. The devices can be used with conventional multi-sample needles up to 1 ½ inches in length.

DEVICE INDICATIONS FOR USE

The RELI® Safety Blood Collection Tube Holder and the RELI® Blood Collection Tube Holder are intended to enable withdrawal of blood samples from a patient.

The RELI® Safety Blood Collection Tube Holder is designed to prevent accidental needle stick injuries.

COMPARISON OF TECHNICAL CHARACTERISTICS

Parameter	Subject Device	Predicate Device	Comparison
510(k) Number	K173279	K113505	
Indications for Use	The RELI® Safety Blood Collection Tube Holder and the RELI® Blood Collection Tube Holder are intended to enable withdrawal of blood samples from a patient. The RELI® Safety Blood Collection Tube Holder is designed to prevent accidental needle stick injuries.	The VACUETTE® QUICKSHIELD with SNAPPY Tube Holder is to be used together only with VACUETTE® Blood Collection Needles and VACUETTE® Blood Collection Tubes as a system in routine venipuncture procedures. These devices are to be used by properly trained healthcare professionals only in accordance with these instructions.	Similar
Material			
Holder Material	Polypropylene	Polypropylene	Same
Sharp Safety Feature	Polypropylene	Polypropylene	Same
Safety Feature Design			
Principle of Operation	External safety feature designed to fully encapsulate the needle by manual activation. Safety feature spins 180^0 for ease of positioning during use.	External safety feature designed to fully encapsulate the needle by manual activation. Safety feature spins 180^0 for ease of positioning during use.	Same

	A one-handed activation by thumb or pressing the safety shield on the needle on a flat surface.	A one-handed activation by thumb or pressing the safety shield on the needle on a flat surface.	
Sharp Activation Feature	Stable surface or thumb	Stable surface or thumb	Same
Sterilization	Non-sterile	Non-sterile	Same
Needle Recommendation and sizes	For use with conventional multi-sample needles up to 1 ½ inches in length.	For use only with VACUETTE® Blood Collection Needle with View Window (K061483) and VACUETTE® Multi-Sample Needles (K973620).	Same except the RELI® can be used with standard blood collection needles not to exceed 1 ½" in length
Biocompatibility	Device does not contact patient	Device does not contact patient	Same

Discussion of Similarities and Difference:
Similarities:
The RELI® Safety Blood Collection Tube Holder is similar to the predicate device in Indications for Use, Principle of Operation of the safety feature and technological characteristics.

Differences:

The RELI® Safety Blood Collection Tube Holder differs from the predicate device in the use of standard multi sample needles not to exceed 1½" length rather than a proprietary needle supplied with the holder. The difference does not introduce different questions of safety and effectiveness.

Performance Testing – Non-Clinical

The following performance testing was conducted on the RELI® Safety Blood Collection Tube Holder to demonstrate substantial equivalence of the subject device K173279.

Standard	Title
ISO 80369-7	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications • Mating with the bidirectional blood collection needle
ASTM F 1980-2007	Standard guide for accelerated aging of sterile barrier systems for medical devices. (Sterility) • Safety Blood Collection Device – 3 year accelerated aging • Safety Blood Collection Device – 5 year accelerated aging

Performance Simulated use testing by the intended users was completed using 500 samples of the RELI® Safety Blood Collection Tube Holder with 100% successful use

with no device failures and no incomplete enclosures of the sharp.

CONCLUSION

Based upon the technology characteristics and safety performance testing, it is the conclusion of MYCO Medical Supplies, Inc., that the RELI® Safety Blood Collection Tube Holder and the RELI® Blood Collection Tube Holder are substantially equivalent to the predicate device.