

K173279
510k Summary

SPONSOR

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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	<p>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.</p> <p>The RELI® Safety Blood Collection Tube Holder is designed to prevent accidental needle stick injuries.</p>	<p>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.</p>	Similar
Material			
Holder Material	Polypropylene	Polypropylene	Same
Sharp Safety Feature	Polypropylene	Polypropylene	Same
Safety Feature Design			
Principle of Operation	<p>External safety feature designed to fully encapsulate the needle by manual activation. Safety feature spins 180° for ease of positioning during use.</p>	<p>External safety feature designed to fully encapsulate the needle by manual activation. Safety feature spins 180° for ease of positioning during use.</p>	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 <ul style="list-style-type: none"> • Mating with the bidirectional blood collection needle
ASTM F 1980-2007	Standard guide for accelerated aging of sterile barrier systems for medical devices. (Sterility) <ul style="list-style-type: none"> • 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.