May 16, 2022

Yomura Technologies Inc.
℅ Anita Chen
Official Correspondent
ZhengCheng Consulting Corporation
No.19, 335 Lane, Fu-Xi Road, Shulin District
New Taipei City, 23871
Taiwan

Re: K210516
Trade/Device Name: Clicky Cross™
Regulation Number: 21 CFR 880.5440
Regulation Name: Stopcock, I.V set
Regulatory Class: Class II
Product Code: FMG
Dated: March 22, 2022
Received: April 14, 2022

Dear Anita Chen:

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
For Payal Patel
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)*
K210516

Device Name
Clicky Cross™

Indications for Use *(Describe)*
Clicky Cross™ is indicated for fluid flow control and for providing access port(s) for administration of solutions in a limited contact duration (24 hours or less). Typical uses include pressure monitoring, intravenous fluid administration, transfusion and infusion of nutritive or medicinal fluids.

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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K210516.510K Summary

Date Prepared May 16, 2022

1. Manufacturer

Mailing Address	Yomura Technologies Inc. Address: No.8, Gong 8th Rd., LinKou Dist., New Taipei City 244, Taiwan Web: www.yomura.com.tw Phone: 02-86013839 Fax: 02-86013833 Establishment Registration No.: 1st
Contact Person	Mrs. Anita Chen/ Regulatory Adviser of Yomura Technologies Inc.
Phone:	+886(0) 939-855-759
E-mail:	m9104303@gmail.com

2 Device Name

Proprietary Name:	Clicky Cross™
Common or usual name	I.V. Set Stopcock
Product Code	FMG
Device	Clicky Cross™
Regulation Number	21 CFR 880.5440
Regulation Name	Intravascular administration set
Device Class	II
Classification Panel	General Hospital

3 Predicate Device

510(k) number:	K111016
Trade or proprietary	Safeport Manifold™

or model name:

4 Device Description: Clicky Cross™ is indicated for fluid flow control and for providing access port(s) for administration of solutions. Typical uses include pressure monitoring, intravenous fluid administration, transfusion and infusion of nutritive or medicinal fluids.

Yomura Clicky Cross™ is a new medical device using as flow control switch and is developed by Yomura Technologies Inc.

Click-release process via one-handed operation

Less leakage issue than currently commercial products

Stopcock system for I.V. set and other application

Suitable for all current pressure infusion system

There are two types of fitting end (Barb /Luer) for normal I.V. infusion sets. In order to meet the requirement of I.V. infusion set, here we provide two different types of fitting end (Barb/Luer).

Types of Fitting end

	Barb	Luer
Specification and Difference	A barb connector is made and held in place by one or more continuous radial serrations or ridges surrounding a hollow tube through which fluid and air flow can take place.	A Luer connector is a small-bore connector that contains a conical mating surface with a 6% taper. The threads contain male type and female type.
Usage	Intravascular or hypodermic applications of	Intravascular or hypodermic applications of

	medical devices and related accessories.	medical devices and related accessories.

5. Substantial Equivalence Discussion

Characteristic	Predicate Device Safeport Manifold™ K111016	Subject Device Device Name K210516
Indication for Use	New modified SafePort Manifold (Stopcock) serve as a flow control and a conduit device for I.V fluid delivery to the patient's vascular system. The product is intended for delivering of I.V. drugs or fluids, allowing gravity feed, sampling bolus injection and elimination or reflux of fluid during operation.	Clicky Cross™ is indicated for fluid flow control and for providing access port(s) for administration of solutions in a limited contact duration (24 hours or less). Typical uses include pressure monitoring, intravenous fluid administration, transfusion and infusion of nutritive or medicinal fluids.
Prescription Only or Over the counter	Prescription Only	Prescription Only

Clicky Cross™ has the same intended use as the claimed predicate device, Safeport Manifold™ (K111016). Although there is a slightly different technological design, as compared to the predicate, the performance data

demonstrates the proposed device performs as safely and effectively as the predicate device. There are only editorial differences to the indications for use statement between the predicate and the subject device which do not change the indications.

Based on the intended use and/or indications for use, technological characteristics, performance testing and comparison to the predicate device, the Clicky Cross™ is substantially equivalent to the predicate device and raises no new questions of safety or effectiveness.

Stopcocks have a body and core, and a small amount of lubricate is applied between stopcock body and core. This device has two styles. One is the female lock and the male lock connection, the other one is barb connector fitting.

6. Technological Characteristics and Substantial Equivalence Comparison with Predicate:

A comparison of the device features, intended use, and other information demonstrates that the Product name is substantially equivalent to the predicate device as summarized in *Table 1*. The differences raise no new question of safety and effectiveness.

Table 1 Comparison table

	Subject Device CLICKY CROSS	Predicate Device Safeport Manifold™	Comment
Product code	FMG	FPA	
Device Name	Clicky Cross™	Safeport Manifold™	

Description	Clicky Cross™ is indicated for fluid flow control and for providing access port(s) for administration of solutions. Typical uses include pressure monitoring, intravenous fluid administration, transfusion and infusion of nutritive or medicinal fluids. Yomura Clicky Cross™ is a new medical device using as flow control switch and is developed by Yomura Technologies Inc. Click-release process via one-handed operation Less leakage issues. Stopcock system for I.V. set and other application Suitable for all current pressure infusion system	SAFEPORT is an intuitive manifold designed for one-way or two-way fluid flow. It is available in 2 and 3 port configurations, with or without swabable valves.	The design is for management the fluid. The intended use is totally the same as: Clicky Cross™ serve as a flow control and a conduit device for I.V fluid delivery to the patient's vascular system.

	There are two types of fitting end (Barb /Luer) for normal I.V. infusion sets. In order to meet the requirement of I.V. infusion set, here we provide two different types of fitting end (Barb/Luer).		
Medical Specialty	General Hospital	General Hospital	Same
Reg. Number	880.5440	880.5440	Same
Class	2	2	same
Materials	PC, POM, TPE	PC, TPE, PP	Different Comment# 1
Design	Stopcocks have a body and core, and a small amount of lubricate is applied between stopcock body and core. This device has two styles. One is the female lock and the male lock connection, the other one is barb connector fitting.	Stopcocks have a body and core, and a small amount of lubricate is applied between stopcock body and core. This device have the female lock and the male lock connection.	Different Comment# 2

Indications for Use	Clicky Cross serve as a flow control and a conduit device for I.V fluid delivery to the patient's vascular system. The product is intended for delivering of I.V. drugs or fluids, allowing gravity feed, sampling bolus injection and elimination or reflux of fluid during operation.	New modified SafePort Manifold (Stopcock) serve as a flow control and a conduit device for I.V fluid delivery to the patient's vascular system. The product is intended for delivering of I.V. drugs or fluids, allowing gravity feed, sampling bolus injection and elimination or reflux of fluid during operation.	Same
Sterility	EO Sterilization	EO Sterilization	Same
Utility	Single use	Single use	Same
Mechanism	Using ratchet and spring, this device follows the rules of Click pen, for locking and releasing the switch to control the flow.	Using handle and rotator, this device can control the flow via rotating the handle to switch on and off.	Different Comment# 3

Discussions of differences in technological characteristics

Comment 1

The different materials POM are use in crenelated bottom as an non-contact part. All materials used in Clicky Cross™ are well known biomaterials with long history of human use. Human contact parts from final device of Clicky Cross™ were evaluated using the FDA 2020 guidance: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management

process". The test results demonstrate that all materials used to construct Clicky Cross™ are biocompatible and safe for human body.

Comment 2

A minor technological difference between the predicate device and subject device is single port for single use. The design is only for management the fluid. The intended use is totally the same as: Clicky Cross™ serve as a flow control and a conduit device for I.V fluid delivery to the patient's vascular system. The product is intended for delivering of I.V. drugs or fluids, allowing gravity feed, sampling bolus injection and elimination or reflux of fluid during operation.

Comment 3

Different design for lock method, but all pass the safety and ISO standards. Lock by switch like a plug in and plug out for lock and open.

7. Performance Testing

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intended use. The following tests were performed on the device.

- ISO 8536-4:2019, Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed
- ISO 80369-7:2016 Small -bore connectors for liquids and gases in healthcare applications-Part 7: Connectors for intravascular or hypodermic applications.

8. Biocompatibility

The biocompatibility evaluation and testing of the Product name was conducted in accordance with the following standards and guidance, as recognized by the FDA:

- ISO 10993-3 Biological evaluation of medical device Part3: Test for genotoxicity, carcinogenicity, and reproductive toxicity
- ISO 10993-5 Biological evaluation of medical device-Part 10: Test for irritation and skin sensitization
- ISO 10993-11, Biological evaluation of medical device-Part 11: Test for systemic toxicity.
- ISO 10993-12 Biological evaluation of medical device -Part 12: sample preparation and reference materials

Particulate testing using USP <788> Particulate Matter in Injection

9. Sterility, Shipping, and shelf Life

The proposed device was evaluated for sterility using ISO 11135:2014 - Sterilization of healthcare products - Ethylene Oxide - Requirements for the for the development, validation and routine control of a sterilization process for medical devices. The validation methos is Overkill Approach (Half-cycle) and residuals of EO <0.01mg/device and ECH <0.04mg/device

- Package Integrity was done after environmental conditioning on final packaged, and sterile devices
- Sterile Barrier Packaging testing performed on proposed device:
    - Seal strength ASTM F88/F88M-15
    - Dye penetration test- ASTM F1929 -12

Shelf life of 3 years is validated using the FDA recognized standard ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

10. Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Clicky Cross™ is substantially equivalent to the Safeport Manifold™ (K111016) with respect to the indications for use, target populations, treatment method, and technological characteristics.