June 28, 2019

Finemedix Co., Ltd.
% Kyungyoon Kang
Consultant
K-Biotech, Inc.
589 Oakwood Drive
Santa Clara, CA 95054

Re: K183021
Trade/Device Name: ClearEndoclip
Regulation Number: 21 CFR§ 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: II
Product Code: PKL, FHN, MND
Dated: May 17, 2019
Received: May 28, 2019

Dear Kyungyoon Kang:

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
Shanil P. Haugen, Ph.D.
Acting Assistant Division Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
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)*
K183021

Device Name
ClearEndoclip

Indications for Use *(Describe)*
ClearEndoclip is intended to be used with FDA-cleared endoscope for endoscopic clip placement within the gastrointestinal tract. It is indicated to be used for

(1) Endoscopic marking
(2) Hemostasis for
(a) Mucosal/sub-mucosal defects < 3cm
(b) Bleeding ulcers
(c)Arteries < 2 mm
(d)Polyps < 1.5 cm in diameter
(e)Diverticula in the colon

(3) Anchoring to affix jejunal feeding tubes to the wall of the small bowel
(4) As a supplementary method, closure of GI tract luminal perforations <20 mm that can be treated conservatively

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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510(k) SUMMARY

Pursuant to Section 510(k) of Chapter V of the Federal Food, Drug, and Cosmetic Act and in accordance with subpart E of Part 807, Title 21 of the Code of Federal Regulations, Finemedix Co., Ltd. submits the following information as premarket notification for the proposed device, ClearEndoclip.

I. SUBMITTER

Company: Finemedix Co., Ltd.
60, Maeyeo-ro, Dong-gu, Daegu
Postal code: 41065, Republic of Korea
Tel: 82-053-741-8388
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510(k) Correspondent: Kyungyoon Kang (Kyungyoon.kang@kbiotechsolutions.com)
Date Prepared: October 24, 2018

II. DEVICE

Trade Name: ClearEndoclip
Common Name: Endoscopic Clipping Device
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal Ligator
Product Code: PKL (hemostatic metal clip for the GI tract), FHN (ligator, hemorrhoidal), MND (ligator, esophageal)
Regulatory Class: II

III. PREDICATE DEVICE

Single Use Repositionable Clip (K123601), Manufacturer: Olympus Medical Systems Corp. This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

ClearEndoclip is a sterile device consisting of a pre-loaded, single-use, endoscopic clipping device with two main components: the (clip-fixing) delivery system and the clip. Clip is pre-loaded in the clip fixing delivery system, connected with an operation wire. Clip will open when the slider of

the clip fixing device is pushed, and closed when it is pulled towards the operator. The clip could be closed and re-opened up to five times. When the slider is pulled further, the clip closes completely. The clip will be released when the slider is pushed. The delivery system consists of a handle and delivery catheter. The delivery system is constructed using stainless steel, HDPE outer sheath, and polypropylene stopper materials. The delivery system will allow for the device to rotate at the distal end. The ClearEndoclip is offered in 165cm and 230cm working lengths.

ClearEndoclip consists of two main components, first, the endoscopic clip, which gets physically deployed and placed as a hemostatic purpose clip in the patient's gastrointestinal tract and second, the delivery system, known as a clip fixing device used to deliver the endoscopic clip under the use of an endoscope.

Functional Descriptions for Critical Components of ClearEndoclip

Component Name	Function
Clip	
Clip	It is detached from the Inner Sheath and holds the tissue by physical force and fixes it to perform hemispheres, indication of lesion and treatment of perforation substantially for the user's intended purpose.
Clip Ring	The clip ring moves according to the slider forward / backward. The Clip is opened / closed by the Clip Ring, and when the Slider is pushed all the way, the Clip is clamped.
Delivery System/Clip Fixing Device	
Inner Sheath (Coil)	The Clip is attached to the end of the Inner Sheath and is connected to the handle to transmit the force and movement from the handle to the Clip.
Outer Sheath (Polyethylene Catheter Tube)	A plastic wrapping around the Inner Sheath and Clip helps protect the endoscope channel.
Tube Joint	When using the product, the outer sheath moves forward and backward to expose the clip from the outer sheath, and to recover the inner sheath into the outer sheath when the product is recovered.
Stopper	It prevents the outer sheath from moving in the direction of Handle when the product is moved and stored, thereby preventing the clip from opening.
Slider	It is used for open/close and detachment of clip.
Handle	It serves to fix this device with user's hand

As far as the raw material compositions are concerned, Clip of ClearEndoclip is constructed with stainless steel material and deployed from the delivery system during the clinical use.ClearEndoclip is engineered such that they can be opened and closed up to five times prior to deployment, aiding in repositioning of the clip at the lesion site. Re-opening, closing, and rotation capability may be limited by clinical circumstances and patient anatomy.

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V. INDICATIONS FOR USE

ClearEndoclip is intended to be used with FDA-cleared endoscope for endoscopic clip placement within the gastrointestinal tract. It is indicated to be used for

(1) Endoscopic marking
(2) Hemostasis for
    (a) Mucosal/sub-mucosal defects < 3cm
    (b) Bleeding ulcers
    (c)Arteries < 2 mm
    (d)Polyps < 1.5 cm in diameter
    (e)Diverticula in the colon

(3) Anchoring to affix jejunal feeding tubes to the wall of the small bowel
(4) As a supplementary method, closure of GI tract luminal perforations <20 mm that can be treated conservatively

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Fundamental technological characteristics of the ClearEndoclip are the same as those of the predicate device, Single Use Repositionable Clip. The operation principle, clinical applications, and instructions for use of the ClearEndoclip is the same as the predicate device, as both devices are used for endoscopic marking, hemostasis for mucosal/submucosal defects in digestive tract by placing an endoscopic clip for the purpose of achieving hemostasis for gastrointestinal bleeding. Both the proposed and predicate devices are provided sterile with ethylene oxide sterilization and used for single use only. Both the proposed and predicate devices consist of the endoscopic clip, which gets physically deployed and placed as hemostatic purpose clip in the patient's gastrointestinal tract and the delivery system, known as a clip fixing device used to deliver the endoscopic clip under the use of an endoscope.

The clinical application and operation principle of the proposed, ClearEndoclip are the same as the predicate device as the stainless mechanical clipping device is used in endoscopy in order to close two mucosal surfaces without the need for surgery or suturing. For both the proposed ClearEndoclip and predicate device, from the mechanical operation- point of view, the endoscopic clipping function is similar to a suture in gross surgical hemostatic applications as it is used to join together disjointed mucosal surfaces that lead to bleeding, however, ClearEndoclip can be applied through the channel of an endoscope under direct visualization, based upon the same clinical and operation principle as the predicate device, Single Use Repositionable Clip.

Both ClearEndoclip and predicate device consist of two main components, first, the endoscopic clip, which gets physically deployed and placed as a hemostatic purpose clip in the patient's gastrointestinal tract and second, the delivery system, known as a clip fixing device used to deliver the endoscopic clip under the use of an endoscope.

Using the delivery system (a clip fixing device) that utilizes the same technological characteristics as the predicate device, in terms of the delivery mechanism to facilitate release of the endoscopic

clip, the Delivery System is designed to control closing and re-opening of the endoscopic clip. As the same as the predicate device, a clip of ClearEndoclip is pre-loaded in its Delivery System (clip fixing device), connected with an operation wire. The manipulation mechanism of opening or closing the clip is also the same as the predicate device, as the ClearEndoclip will open when the handle slider placed in the delivery system (clip fixing device) is pushed and closed when the handle slide is pulled towards the operator. The clip could be closed and re-opened up to five times. When the slider of the delivery system is pulled further, the clip closes completely. The clip will be released when the slider is pushed. As demonstrated herein, the fundamental technological characteristics of ClearEndoclip including the device system construction and operation mechanism, which have been designed in order to meet the indications and user needs are the same as the predicate device.

The operation principles, clinical applications, and instructional for use are all identical between the proposed and predicate devices. As for technological characteristics, the raw material constructions of ClearEndoclip are the same as the reference device, Rotatable Clip Fixing Device (K013066) for Clip and Delivery System (Clip fixing device). The minute difference in the clip Material between ClearEndoclip and predicate, Repositionable Clip (K123601) is effectively addressed by demonstrating favorable biocompatibility test results of the ClearEndoclip performed per the same standards of ISO 10993-1 (2009).

The clinical application and operation principle of the proposed, ClearEndoclip are the same as the predicate device as the stainless mechanical clipping device is used in endoscopy in order to close two mucosal surfaces without the need for surgery or suturing. For both the proposed ClearEndoclip and predicate device, from the mechanical operation- point of view, the endoscopic clipping function is similar to a suture in gross surgical hemostatic applications as it is used to join together disjointed mucosal surfaces that lead to bleeding, however, ClearEndoclip can be applied through the channel of an endoscope under direct visualization, based upon the same clinical and operation principle as the predicate device, Single Use Repositionable Clip.

The only major differences between ClearEndoclip and predicate device lie with the Clip raw material as shown below, however ClearEndoclip shares the same material of Clip as the reference device. The fact ClearEndoclip is assessed MR Unsafe is appropriately indicated in the product label and IFU of ClearEndoclip.

	ClearEndoclip	Predicate Device: Single Use Repositionable Clip (K123601)	Reference Device: Endoscopic Clipping Device (K013066)

Clip Raw Material	Stainless Steel	Elgiloy and 6AI-4V Titanium	Stainless Steel and Silicone
MRI Information	MR Unsafe	MRI conditional	No mention of MRI safety and compatibility

The aforementioned raw material difference with the predicate device is not assessed to raise different questions of safety and effectiveness as ClearEndoclip also demonstrated its conformance to the FDA's same recognized consensus standards of ISO 10993-1 applied to both the predicate and reference devices.

VII. PERFORMANCE DATA

The following performance data were provided in support of this substantial equivalence determination.

Biocompatibility Testing
In accordance with ISO 10993-1: 2009, Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process, the Clip of ClearEndoclip is classified as "Implant Device-Tissue/bone/dentin (Prolonged contact duration) and Delivery System is classified as "Externally Communicating Devices, (<24 hrs of limited contact duration). This is the same classification of the biocompatibility evaluation as the predicate device.

The biocompatibility testing of the ClearEndoclip has been conducted in 2018 in order to ensure FDA's latest consensus standards with respect to biological safety evaluations are met for the proposed device. The favorable biocompatibility test results drawn in 2018 testing provides re-assurance of biologically safe profile of the ClearEndoclip.

Design Verification and Validation Testing
Design Verification and Validation testing were performed to verify that the ClearEndoclip meets the pre-defined safety and performance requirements and demonstrated design input matched with design outputs. Risk management assessment was conducted and appropriate risk mitigation measures were implemented including verifications of the effectiveness of the implemented risk control measures to mitigate the risks identified within the risk management process (per ISO 14971:2012 Medical Devices - Application of Risk Management to Medical Devices).

Three-year accelerated aging performance testing has been completed to affirm the performance profile over the indicated shelf life of ClearEndoclip. Also, Time-zero point performance testing of ClearEndoclip has been conducted with side-by side comparison with the predicate device to evaluate the following critical performance scopes:

- Appearance
- Dimension
- Rotation

- Repeated open/close
- Clamping retention time
- Tensile strength.

Furthermore, physicochemical testing of extractable substance of Delivery System of ClearEndoclip has been conducted in order to verify the safety profile of extracts of ClearEndoclip Delivery System from the standpoint of comprehensive, physicochemical analysis. The favorable test results of the ClearEndoclip, which characterizes the reliable physicochemical profile of extractable substance of Delivery System provide assurance that the ClearEndoclip is safe and appropriate for the indications for use.

The favorable results of the biological safety, design verification performance, and validation testing demonstrate conformance of the proposed ClearEndoclip to the applicable, recognized standards of FDA. The testing results further demonstrate equivalent safety and performance profile as the predicate device, Olympus Single Use Repositionable Clip and the proposed device are subject to the same applicable test standards for safety and performance under FDA's recognized standards including ISO 10993-1 (2009). Therefore, the affirmed safety and performance profile of the ClearEndoclip does not raise different questions in safety and effectiveness compared to the predicate device.

VIII. CONCLUSIONS

The proposed, ClearEndoclip is assessed substantially equivalent to the predicate device given the fact that its indications for use/intended use are identical, and fundamental technological characteristics are the same as the predicate device. The favorable results of the aforementioned safety and performance testing demonstrate conformance to the appropriate recognized standards of FDA, ISO 10993-1 (2009) and further demonstrate that no different questions in safety and effectiveness assessment are being raised compared to the predicate device, Single Use Repositionable Clip.