DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 23, 2015

ConMed Coporation
Ms. Lisa Anderson
Manager, Regulatory Affairs
525 French Road
Utica, New York 13502

Re: K150936
Trade/Device Name: ConMed SureClip Clip Applier
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: FZP
Dated: September 22, 2015
Received: September 24, 2015

Dear Ms. Anderson:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150936

Device Name
ConMed SureClip Clip Applier

Indications for Use *(Describe)*
The SureClip Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary of Safety and Effectiveness

ConMed SureClip Clip Applier

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21CFR 807.92, ConMed Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) number K150936 as of October 21, 2015.

A. Submitter

ConMed Corporation
525 French Road
Utica, NY 13502

Establishment Registration: 1320894

B. Company Contact

Lisa Anderson
Manager, Regulatory Affairs
T: (315) 624-3371
F: (315) 624-3225

C. Device Name

Proprietary Name:	SureClip Clip Applier
Common Name:	Clip Applier
Classification Name:	Implantable Clip
Regulation Number:	878.4300
Product Code:	FZP
Regulatory Class:	II
Panel:	General and Plastic Surgery

D. Predicate Device

Device Name:	LIGAMAX™ 5 Clip Applier
Company Name:	Ethicon Endo-Surgery (“Ethicon”)
510(k):	K110699
Reference devices:	The following reference device is relevant due to its design similarity: LIGAMAX™ 10-M/L (K864102, K830503, and K812291)

E. Device Description

The SureClip Clip Applier (“SureClip”) is comprised of a cartridge (“SureClip Clip Applier Cartridge” or “SureClip Cartridge”) (5mm or 10mm) (Class II) and a handle (Class I). Each cartridge is pre-loaded with 17 implantable titanium clips. The SureClip Clip Applier is intended to apply implantable, medium/large, titanium clips. The clips are manufactured from unalloyed implant grade titanium (ASTM F67 Grade 1 Titanium, UNS R50250). The cartridge must be assembled and locked into the handle. The handle includes a pistol grip trigger and a rotation knob for 360° rotation in either direction. The jaws, which are located at the distal end of the SureClip Cartridge, form each clip as the trigger is actuated.

The handle (Class I device) is exempt from premarket notification procedures per 21 CFR 878.4800 and is only referenced in this submission because it is the mechanism for the advancement and delivery of the implantable clips.

F. Intended Use / Indications for Use

The SureClip Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated.

G. Non-clinical Performance Testing

Non-clinical bench and simulated use testing demonstrate the SureClip Clip Applier is substantially equivalent to the predicate with regard to intended use, materials, technology, and performance. Results of product performance testing confirm that devices comply with design specifications and applicable sections of ISO 11135:2014, AAMI/ANSI ST67:2011, ISO 10993-7:2008, ISO 14971:2007, ASTM F67-13:2013, and ASTM F2503-13:2013. Material analysis and biocompatibility testing prove the patient contacting materials of the SureClip Clip Applier comply with the requirements of ANSI/AAMI/ISO 10993-1:2009(R)/2013. Performance testing, including clip burst testing, clip retention, and animal testing (implantation) per Good Laboratory Practice 21 CFR Part 58, demonstrates the device performance is substantially equivalent to the predicate devices.

H. Substantial Equivalence

The SureClip Clip Applier is compared to the predicate device, Ethicon's 5mm Clip Applier (K110699). It is also compared to Ethicon's 10mm Clip Applier (K864102) which is used as a reference device specifically for its size. Comparison of device features and side-by-side comparison testing conducted for clip applier performance demonstrate that SureClip Clip Applier is substantially equivalent to Ethicon's Clip Applier for both the 5mm and 10mm regarding intended use/indications for use, technology, and performance specifications.

Technological Characteristics

The new/different technological characteristics presented by the SureClip Clip Applier are limited to design features considered to be "customer preference" driven, including the new warning clips that provide immediate, visual, feedback; cartridge assembly and disassembly capability; clip retention features; clip feeding sequence; distinctive ratcheting and "Ratchet Release Point," and the jaw lockout feature.

The SureClip Clip Applier is identical to the predicate in that it is made up of the same operational components such as the clip carrier (cartridge/shaft) which houses the implantable clips, pistol grip handle with trigger and rotation knob, ratcheting feedback feature ["Ratchet Release Point"], and lockout safety feature to prevent empty jaws from closing on a structure or vessel. Materials include various polymers, stainless steel, and implantable titanium (Grade 1) ligation clips. All patient contacting materials are biocompatible per ANSI/AAMI/ISO 10993-1:2009(R)2013. Product performance and animal testing demonstrate the safe and effective application of the new design features for the same intended use as the predicate device.

I. Conclusion

The differences between the predicate and the SureClip Clip Applier do not raise any new risks of safety or efficacy. Supporting information per this premarket submission confirms that the SureClip Clip Applier is safe and effective for its intended use, and is substantially equivalent to the predicate device.