November 15, 2018

Amsel Medical Corporation
% Mr. Leo L. Basta
Northstar Biomedical Associates
171 Hamilton Street
Cambridge, Massachusetts 02139

Re: K180650
Trade/Device Name: Amsel Endo Occluder device
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: FZP
Dated: October 12, 2018
Received: October 15, 2018

Dear Mr. Basta:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180650

Device Name
Amsel Endo Occluder device

Indications for Use *(Describe)*
Amsel Endo Occluder device is an endoscopic ligating clip applier and clips, which is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated and within the size range of 2.0mm to 7.0mm diameter.

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.

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

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

AMSEL ENDO OCCLUDER DEVICE

Date prepared: November 14, 2018

I. Submitter's name and address

Establishment name:	Amsel Medical Corp.
Establishment address:	171 Hamilton Street Cambridge, MA 02139 Tel:(617)395-8825 Fax: (617) 608-9080
Establishment registration:	3008989837
Primary Contact person:	Leo Basta Northstar Biomedical Associates 93 Benefit Street Providence, RI 02904 (617) 834.9866 lbasta@northstarbiomedical.com

II. Device information

Amsel Endo Occluder device	
Trade name:	Implantable Clip
Device Classification Name	Class II
Device Class	General & Plastic Surgery
Classification Panel	FZP
Product Code	21CFR 892.4300
Regulation Description	

III. Device Description:

Amsel Endo Occluder device is an endoscopic ligating clip applier that is pre-loaded with four sterile ligating clips.

Amsel Endo Occluder device is intended to be used during endoscopic procedures (such as Laparoscopic procedures), for permanent secure occlusion of blood vessels and ductal structures. The device is a mechanical occlusion clip that when deployed transfixes the target vessel while clamping it shut.

Amsel Endo Occluder contains two main components:

- *Ligating (Occluder) Clips-* each sterile clip consists of two "star" shaped compression elements and titanium fine rod which connects and locks the compression element tighter.
- *Applier (device delivery)-* a sterile, single patient use, disposable surgical applier designed to provide a means of ligation through an appropriately sized trocar. The applier is pre-loaded with 4 clips.

IV. Intended use:

Amsel Endo Occluder device is an endoscopic ligating clip applier and clips, which is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated and within the size range of 2.0mm to 7.0mm diameter.

V. Predicate Devices:

The ***Amsel Endo Occluder*** device is substantially equivalent to the following market-cleared devices:

Table 2-1 Predicates table

	Device Name	Manufacturer	510k No	Date of Clearance
Primary predicate	LIGACLIP 5M/L Endoscopic Multiple Clip	Ethicon	K050344	March 14, 2005
Predicate	Amsel Occluder Device	Amsel Medical Corporation	K149032	January 23,2015

The proposed ***Amsel Endo Occluder*** device and its primary predicate device, LIGACLIP 5M/L Endoscopic Multiple Clip (K050344) are substantially equivalent in regards to their intended uses, clinical indications, principle of operation and fundamental technology principles.

The proposed ***Amsel Endo Occluder*** device and its predicate device, Amsel Occluder Device (K149032) are substantially equivalent in regards to their clinical indications, principle of operation, device design and material and fundamental technology principles.

VI. Substantial Equivalence to Predicate Devices

Feature	The proposed device: Amsel Endo Occluder	Primary Predicate: LIGACLIP 5M/L Endoscopic Multiple Clip (K050344)	Predicate Amsel Occluder Device (K149032)
Device Classification Name	Clip, Implantable clip	Clip, Implantable clip	Clip, Implantable clip
Device Class	Class II	Class II	Class II
Classification Panel	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery
Product Code	FZP	FZP	FZP
Regulation Description	Implantable clip	Implantable clip	Implantable clip
Regulation Number	21 CFR 878.4300	21 CFR 878.4300	21 CFR 878.4300
Intended use	Vessel ligation or occlusion	Vessel ligation or occlusion	Vessel ligation or occlusion
Indication for Use	Amsel Endo Occluder device is an endoscopic ligating clip applier and clips, which is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated and .	LIGACLIP 5M/L 5mm Endoscopic Multiple Clip is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated. The tissue being ligated should be consistent with	The Amsel Occluder Device is intended for use in open general surgery procedures on tubular structures or vessels wherever a metal ligating clip is indicated and within the size range of

	within the size range of 2.0mm to 7.0mm diameter	the size of the clip.	2.0mm to 7.0mm diameter.
Environment of use	Hospitals and surgery center	Hospitals and surgery center	Hospitals and surgery center
Clinical procedure	Endoscopy procedure	Endoscopy procedure	Open general surgery
Pre-loaded/Loaded in OR	Pre -loaded	Loaded in the OR	Pre-loaded
Clip Size	One size	M,L	One Size
Length of Clipping	5.0mm	5.5mm	5.0mm
Compatible to Trocar	Yes. Trocar size 5mm	Yes. Trocar size 5mm	No
Secure to vessel mechanism	External compressive force on the vessel (By Press)	External compressive force on the vessel (By Press)	External compressive force on the vessel (By Press)
Closure method	Penetrating through (Transfixing) the vessel using a needle and then compressing and locking the two occlusion elements; external vessel compression	External vessel compression	Penetrating through (Transfixing) the vessel using a needle and then compressing and locking the two occlusion elements; external vessel compression
Clip Material	Nitinol and Titanium	Titanium	Nitinol and Titanium
Single Patient use, Disposable	Yes	Yes	Yes
Sterilization	Sterilized by ETO	Sterilized by ETO	Sterilized by ETO
Prescription use	The device should be used only by trained surgeon under a physician order.	The device should be used only by trained surgeon under a physician order.	The device should be used only by trained surgeon under a physician order.

In conclusion, Amsel Medical Corporation believes that the ***Amsel Endo Occluder*** device does not introduce any new potential safety and/or effectiveness issues and is substantially equivalent to the identified predicate devices, LIGACLIP 5M/L Endoscopic Multiple Clip (K050344) and Amsel Occluder Device (K149032).

VII. Brief discussion of the nonclinical tests submitted, referenced or relied on

Non-clinical performance testing has been performed on ***Amsel Endo Occluder*** device and demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance document:

ISO 14971 :20072012	Medical devices – Application of risk management to medical devices
IS0 11135-1:2014	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices (Sterility)
ISO 10993-1:2009	Biological Evaluation of Medical Devices -- Part 1: Evaluation and Testing Within A Risk Management Process
ANSI/AAMI/ISO 10993-7: 2012	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals.
ASTM F1980-07	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. (Sterility).
AMI / ANSI / IS0 11607-1:2006	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials (sterility).
ASTM F-2063	Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants
ASTM F899 – 12b	Standard Specifications for Wrought Stainless Steels for Surgical Instruments
ASTM 2129-17	Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices
ASTM F3044-14	Test Method for Standard Test Method for Evaluating the Potential for Galvanic Corrosion for Medical Implants

Amsel Endo Occluder device was tested in accordance with Amsel verification and validation processes. Verification and Validation tests have been performed to address its intended use, the technological characteristics claims, requirement specifications and the risk management results. The test results in this 510(k)-premarket notification demonstrate that ***Amsel Endo Occluder***:

- Complies with the aforementioned international and FDA-recognized consensus standards and FDA guidance document, and
- Meets the acceptance criteria and is adequate for its intended use and specifications.

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VIII. Brief discussion of clinical tests submitted, referenced or relied on

The subject of this premarket submission, ***Amsel Endo Occluder*** device did not require clinical studies to support equivalence.

Preclinical *in-vivo* tests, including acute and chronic tests, were conducted in order to demonstrate the safety and effectiveness of ***Amsel Endo Occluder*** device in terms of occlusion performance.

IX. The conclusions drawn from the nonclinical and clinical tests

Verification and Validation (V&V) activities required to establish performance and functionality of ***Amsel Endo Occluder*** device were performed. Testing performed demonstrated the ***Amsel Endo Occluder*** device meets all defined functionality requirements and performance claims.

X. Overall conclusion:

The ***Amsel Endo Occluder*** device is substantially equivalence to the identified predicate device, LIGACLIP 5M/L Endoscopic Multiple Clip (K050344) and Amsel Occluder Device (K149032) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. Additionally, verification and validation testing demonstrate the safety and efficacy of the device to meet its intended use and specifications.

Amsel Medical believes that the proposed device**,** ***Amsel Endo Occluder*** device, is substantially equivalent to its identified predicate device and is as safe and effective as its

predicate device without raising any new safety and/or effectiveness concerns.