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

August 30, 2016

Miret Surgical Inc.
% Jerzy Wojcik
EdgeOne Medical
455 N Campbell Ave, #2N
Chicago, Illinois 60612

Re: K160149
Trade/Device Name: Miret Surgical Instruments (Miret Grasper, Alligator; and Miret Grasper, Maryland)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: OCW
Dated: August 15, 2016
Received: August 16, 2016

Dear Jerzy Wojcik:

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" (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 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,

Christopher J. Ronk -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)*
K160149

Device Name
Miret Surgical Instruments

Indications for Use *(Describe)*
The Miret Surgical Instruments are a family of minimally invasive devices with the means to penetrate soft tissue to access certain areas of the human anatomy. The devices are used to grasp, hold and manipulate soft tissues.

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

Date Summary Prepared: January 18, 2016

510(k) Owner: Miret Surgical Inc

Contact Person:
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Device Name:

Device Name:	Miret Surgical Instruments
Trade Name:	Miret Surgical Instruments
Common Name:	Endoscopic tissue approximation device
Classification:	876.1500
Class:	2
Product Code:	OCW

Predicate Device(s): Primary Predicate

K070686 MINI LAP INSTRUMENTS

Device Description: Fabricated from a stainless steel alloy, Miret Surgical Instruments are single-use disposable devices designed for grasping, holding and manipulating tissue. They consist of an integrated needle/cannula shaft that attaches to a working instrument.

The shaft can be introduced percutaneously to the surgical site, after which the working instrument can be operated. The working instrument is controlled through a handle and locking mechanism on the proximal end of the device. The Miret Surgical Instruments can be used in a variety of surgical applications, including laparoscopic surgery after

insufflation, and are available in either a Maryland or Alligator grasper configuration.

Statement of Intended Use: The Miret Surgical Instruments are a family of minimally invasive devices with the means to penetrate soft tissue to access certain areas of the human anatomy. The devices are used to grasp, hold and manipulate soft tissues.

Comparison of Technological Characteristics with Predicate Devices: The proposed Miret Surgical Instruments have the same technology, indications and fundamental characteristics as the predicate. Both are intended to be used in minimally invasive surgeries. Both are composed of patient contact metal with plastic handles and achieve the same function of opening and closing the graspers by hand operation. Both are available in various grasper designs such as Maryland or Alligator, and are sterile, single-use, disposable devices.

Non-Clinical Performance Data: Non-clinical performance testing was performed to verify that the performance of the Miret Surgical Instrument is substantially equivalent to currently marketed laparoscopic instrument, and specifically substantially equivalent to the MINI LAP Instruments (K070686).

Evaluation	**Conclusion**
Ability of grasper to grip tissue	Equivalent or better
Ability to actuate grasper after navigation to surgical site	Equivalent or better
Simulated use	Equivalent or better

Overall Conclusions: Based on the indications for use, technological characteristics, and comparison to predicate devices, the Miret Surgical Instruments have been shown to be substantially equivalent to the predicate and is safe and effective for its intended use.