December 7, 2018

Agency for Medical Innovations GmbH
% Allison C. Komiyama, Ph.D., R.A.C.
Principal Consultant
AcKnowledge Regulatory Strategies, LLC
2251 San Diego Ave., Suite B-257
San Diego, CA 92110

Re: K182664
Trade/Device Name: FiXcision
Regulation Number: 21 CFR§ 876.4730
Regulation Name: Manual Gastroenterology-Urology Surgical Instrument and Accessories
Regulatory Class: I
Product Code: KOA
Dated: September 21, 2018
Received: September 25, 2018

Dear Allison C. Komiyama:

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,

Jeffrey W.
Cooper -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K182664

Device Name
FiXcision

Indications for Use *(Describe)*
The A.M.I. FiXcision device is intended to be used by qualified physicians to provide access of internal structures and for manipulating soft tissue (cutting) for treatment of simple anal fistulae.

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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510(k) Summary
K182664

DATE PREPARED
December 5, 2018

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PROPRIETARY NAME OF SUBJECT DEVICE
FiXcision

COMMON NAME
Surgical Instruments, Gastroenterology-Urology, Manual (And Accessories)

DEVICE CLASSIFICATION
Manual gastroenterology-urology surgical instrument and accessories
(21 CFR 876.4730, Product Code KOA, Class I)

PREMARKET REVIEW
ODE/DRGUD/GEDB
Gastroenterology Devices Branch

INDICATIONS FOR USE
The A.M.I. FiXcision device is intended to be used by qualified physicians to provide access of internal structures and for manipulating soft tissue (cutting) for treatment of simple anal fistulae.

510(k) Summary

DEVICE DESCRIPTION

FiXcision is an EO-sterilized, single use, multi-part, manual cutting instrument for use during anal fistula surgery in coloproctology. FiXcision enables circumferential tissue removal for the treatment of simple anal fistulae. The four components include the following:

- Probe: Component made of stainless steel that passes through the fistula tract.
- Guide: Component made of stainless steel that compresses tissue within the fistula tract.
- Base Plate: Component made of stainless steel that acts as a stop for the Circular Cutter.
- Circular Cutter: Component made of stainless steel and polyvinyl chloride (PVC-U). The Circular Cutter cuts tissue from fistula tract. The distal end of the Circular Cutter has a protective cap made of silicone that is removed prior to use.

PREDICATE DEVICE IDENTIFICATION

The FiXcision device is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K760715	Flexible Cutting Scissors / V. Mueller O.V. Baxter Healthcare Corp.	✓

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for FiXcision. The following non-clinical testing has been performed in order to demonstrate equivalence to the predicate device:

- Sterilization and shelf life validation
- Biocompatibility testing:
  - Cytotoxicity per ISO 10993-5
  - Sensitization per 10993-10
  - Irritation per 10993-10
- Performance testing (bench):
  - Design validation
    - Wear of the cutting edge of the Circular Cutter
    - Tensile force of the Circular Cutter
    - Bending test for the Probe
    - Strength of screwed end of the Guide
  - Usability per IEC 62366-1

EQUIVALENCE TO PREDICATE DEVICE

The subject device has equivalent intended use and similar technological characteristics as the device cleared in K760715. Unlike the predicate device that had a general intended use for cutting, FiXcision has specific indications to only be used on patients who have simple anal fistulae. Unlike the straight blade(s) of the predicate, FiXcision

cuts tissue using a tubular blade. This technological characteristic has undergone testing to ensure the device is substantially equivalent to the predicate.

CONCLUSION

Based on the testing performed, including biocompatibility, sterilization and shelf life validation, and non-clinical performance testing (bench), it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device. The similar intended use, technological characteristics, and performance characteristics for the proposed FiXcision device are assessed to be substantially equivalent to the predicate device.