January 8, 2020

Baxter Healthcare Corporation
Ms. Jeanette Licata
Sr. Associate, Regulatory Affairs
32650 N. Wilson Road
Round Lake, Illinois 60073

Re: K193137
Trade/Device Name: EASYGRIP FLO-41 Precision MIS Delivery System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: November 11, 2019
Received: November 13, 2019

Dear Ms. Licata:

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 and Part 809; 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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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)*
K193137

Device Name
EASYGRIP FLO-41 Precision MIS Delivery System

Indications for Use *(Describe)*
The EASYGRIP FLO-41 Precision MIS Delivery System is indicated for delivering compatible hemostatic agents to bleeding sites through a 5 mm or larger trocar.

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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Section 5. 510(k) Summary

November 11, 2019

SPONSOR:

Baxter Healthcare Corporation
32650 N. Wilson Road
Round Lake, Illinois 60073

Phone: (224) 948 3996
Fax: (224) 270 4119

SPONSOR CONTACT:

Jeanette Licata
Sr. Regulatory Associate

Phone: (224) 948 3996
Fax: (224) 270 4119
Email: jeanette_licata@baxter.com

IDENTIFICATION OF THE DEVICE:

Common Name: Endoscopic Applicator
Trade/Device Name: EASYGRIP FLO-41 Precision MIS Delivery System
Classification Panel: 79 General and Plastic Surgery
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ

Table 1. Code Number for EasyGrip FLO-41 Precision MIS Delivery System

Code Number	Name
ADS201897	EASYGRIP FLO-41 Precision MIS Delivery System

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PREDICATE DEVICE:

The predicate device, the Malleable Tip Endoscopic Applicator, is manufactured by Micromedics Inc., dba Nordson Medical.

Table 2. Predicate Device

Trade Name	Company	Predicate 510(k)	Clearance Date
Malleable Tip Endoscopic Applicator	Micromedics, Inc. dba Nordson Medical	K123847	01/08/2013

REASON FOR SUBMISSION:

The basis for this premarket notification is a modification to the design of the Malleable Tip Endoscopic Applicator to allow for one handed application of compatible hemostatic agents to bleeding sites.

INDICATIONS FOR USE:

The EASYGRIP FLO-41 Precision MIS Delivery System is indicated for delivering compatible hemostatic agents to bleeding sites through a 5mm or larger trocar.

DESCRIPTION OF THE DEVICE:

The EASYGRIP FLO-41 Precision MIS Delivery System (EASYGRIP FLO-41 System) is a sterile, single-use device that consists of two components: (1) one applicator device with a 41 cm long cannula (5 mm outer diameter) and (2) one empty 1.5 mL syringe.

The EASYGRIP FLO-41 System is used to deliver compatible hemostatic agents to bleeding sites. After preparation of compatible hemostatic agent per the instructions, the proposed device is filled by first attaching the compatible hemostatic agent syringe to the syringe port by a Luer lock connection and depressing the syringe plunger, which then fills the enclosed 5 mL reservoir syringe with the hemostatic matrix. The delivery of hemostatic agent to the bleeding site would be performed by actuating the device trigger handle, which can be performed using one hand. As an optional step, if application of the residual hemostatic agent that remains within the cannula is needed, an empty, disposable 1.5 mL syringe is provided and would be filled with non-heparinized saline. Following the same steps as with the hemostatic agent, the reservoir syringe would be filled with 1.5 mL of saline and the residual hemostatic agent would be expelled from the cannula by actuating the device trigger handle.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed device is substantially equivalent to the predicate device, previously cleared under 510(k) premarket notification K123847 on January 8, 2013. The intended use and function of the proposed device are equivalent to the predicate device.

Table 3 is a device comparison table outlining the differences between the predicate and proposed devices.

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Table 3. Device Comparison

Features	Predicate Device Cleared under K123847	Proposed Device EasyGrip FLO-41 Precision MIS Delivery System	Assessment of Differences
Intended Use	The Malleable Tip Endoscopic Applicator is intended for use in delivering hemostatic agents to bleeding surgical sites through a 5mm or larger trocar	The EASYGRIP FLO-41 Precision MIS Delivery System is intended for delivering compatible hemostatic agents to bleeding sites through a 5mm or larger trocar.	Not Applicable
Indications for Use	The Malleable Tip Endoscopic Applicator is intended for use in delivering hemostatic agents to bleeding surgical sites through a 5mm or larger trocar	The EASYGRIP FLO-41 Precision MIS Delivery System is indicated for delivering compatible hemostatic agents to bleeding sites through a 5mm or larger trocar.	Not Applicable
Sterile	Yes	Same	Not Applicable
Non-Pyrogenic	Yes	Same	Not Applicable
Single Use	Yes	Same	Not Applicable
Materials (Fluid Path)			
Cannula	Sheath (Tube): PolyMed® High strength fiber with vinyl ester resin	Sheath (Tube): Same	The proposed device's collar, malleable tip tubing and adhesive material have passed functional testing for their intended use. Additional testing has confirmed the biocompatibility of the materials. The different technological characteristics of the proposed device do not raise different questions of safety and effectiveness.
	Collar: Unknown	Collar: Stainless Steel	
	Malleable Tip Tubing: Unknown	Malleable Tip Tubing: Polyurethane tubing with encapsulated 304 Stainless Steel wire Adhesive Epoxy	

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Table 3. Device Comparison

Features	Predicate Device Cleared under K123847	Proposed Device EasyGrip FLO-41 Precision MIS Delivery System	Assessment of Differences
		(cannula/collar and collar/malleable tip) Loctite M-31CL	
Luer Lock Connector (overmolded on Cannula)	Acrylonitrile Butadiene Styrene (ABS)	Same	Not Applicable
Stylet	PolyMed® composite rod Acrylonitrile Butadiene Styrene (ABS) tip Acrylonitrile Butadiene Styrene (ABS) handle	Proposed device doesn't have a stylet	The proposed device doesn't have a stylet. Design control activities have been conducted and have confirmed that the different technological characteristics of the new device do not raise different questions of safety and effectiveness.
1.5 mL empty flush syringe	Not applicable	Barrel: Polycarbonate Plunger:Polycarbonate + 10% Glass Filled Piston Seal:Thermoplastic elastomer	The predicate device does not have a 1.5 mL empty flush syringe. Design control activities have been conducted and have confirmed that the different technological characteristics of the new device do not raise different questions of safety and effectiveness.

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Table 3. Device Comparison

Features	Predicate Device Cleared under K123847	Proposed Device EasyGrip FLO-41 Precision MIS Delivery System	Assessment of Differences
Dual check valve	Not applicable	Body: Polycarbonate Swivel Nut: Copolyester Female Luer Ports: Polycarbonate Valve: Silicone	The predicate device does not have a dual check valve. Design control activities have been conducted and have confirmed that the different technological characteristics of the new device do not raise different questions of safety and effectiveness.
Reservoir Syringe	Not applicable	Plunger: Polypropylene homopolymer Barrel: Polypropylene Piston Seal: Thermoplastic elastomer	The predicate device does not have a reservoir syringe. Design control activities have been conducted and have confirmed that the different technological characteristics of the new device do not raise different questions of safety and effectiveness.

SUMMARY OF SUPPORTING DATA:

Baxter Healthcare Corporation conducts risk analyses and design verification tests based on the result of these analyses. All test results meet their acceptance criteria and support that the proposed device is appropriately designed for its intended use.

Performance Data:

The following bench tests (Table 4) were conducted to evaluate the functional performance of the EASYGRIP FLO-41 Precision MIS Delivery System. All tests met the acceptance criteria.

Table 4. Performance Data Summary for Proposed Device

Test	Acceptance Criteria
Trigger Force to Deliver Hemostatic Matrix	The Trigger Force Test evaluated with 95% confidence that for 95% of the devices the force required to deliver hemostatic matrix is less than 30 lbf.
Malleable Tip Bend and Robustness Test	The Malleable Tip Bend and Robustness Test demonstrated with 95% confidence that 95% of the malleable tips shall not kink when bent to 90 degrees and will be able to deliver the product.
Device Interface Leak test	The Device Interface Leak Test demonstrated with 95% confidence that 95% of the device interfaces between the cannula, dual check valve and syringe will not leak during the use of the device.
Saline Retainment inside the Device after Residual Flush	The Saline Retainment Test demonstrated with 95% confidence that 90% of the devices would retain the 1.5 ml Saline within the device after the residual hemostatic matrix is delivered.
Cannula Bend Test at Various Trocar Positions	The Cannula Bend Test demonstrated with 95% confidence that 95% of the devices would not break and leak at the device connections after being subjected to the bend test.
Device Tensile Strength	The Device Tensile Strength Test demonstrated with 95% confidence that 95% of the device connections can withstand the tensile pull force of 5lb without failure.
Consecutive Delivery of Hemostatic Agent	The Consecutive Delivery Test demonstrated with 95% confidence that 95% of the devices will be able to

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Table 4. Performance Data Summary for Proposed Device

Test	Acceptance Criteria
	successfully deliver 3 consecutive applications of the hemostatic matrix without device failure (Failure is defined as unable to deliver the product, mechanical component failure, syringe damage leak at connections, clogged tip).
Intermittent Delivery of Hemostatic Agent	The Intermittent Delivery Test demonstrated with 95% confidence that 95% of the devices were able to deliver the hemostatic matrix over the range of 2 hours without device failure (Failure is defined as unable to deliver the product, mechanical component failure, syringe damage leak at connections, clogged tip).
Device Functionality to Start and Stop Delivery of Hemostatic Matrix	The Device Functionality Test demonstrated with 95% confidence that 95% of the devices were able to stop the delivery of the hemostatic matrix through the device within 5 seconds, when the force on the trigger was released from the device.
Dual Check Valve Function Test	The Dual Check Valve Test demonstrated with 95% confidence that 90% of the devices would require less than 17.3lbf force to fill the reservoir syringe with hemostatic matrix through the check valve.
Material Compatibility with Thrombin	The Material Compatibility with Thrombin Test demonstrated with 95% confidence that for 90% of the devices there is no statistical significance in the thrombin activity between the thrombin which has been collected from the device after 2 hours of storage to the respective control.
Cannula Luer Test for compliance with ISO 80369-7	Tested in accordance to ISO 80369-7
1.5 ml Syringe Test for compliance to ISO 80369-7	Tested in accordance to ISO 80369-7
Dual Check Valve Test for compliance to ISO 594-1 and ISO 594-2	Tested in accordance to ISO 594-1 and 594-2
Reservoir Syringe Fill Capacity	The Reservoir Syringe Fill Capacity Test demonstrated with 95% confidence that 90% of the reservoir syringes can accommodate at least 5ml of product.

Biocompatibility:

For the device fluid path, biocompatibility assessments were conducted to meet an ISO 10993-1 Qualification of External Communicating Devices; Tissue, Bone, Dentin; Limited (≤24 hrs) contact. Biocompatibility assessments were conducted on final, finished and sterilized devices for all fluid path materials of EASYGRIP FLO-41 Precision MIS Delivery System. The following tests were conducted as part of the biocompatibility testing for the device fluid path of the EASYGRIP FLO-41 Precision MIS Delivery System:

- Cytotoxicity ISO 10993-5
- Sensitization ISO 10993-10
- Intracutaneous (Irritation) Reactivity ISO 10993-10
- Systemic Toxicity (acute) ISO 10993-11
- Materials Mediated Pyrogen ISO 10993-11

Based upon the results of this limited duration, external communicating, tissue, bone, dentin testing, the EASYGRIP FLO-41 Precision MIS Delivery System has been shown to be biocompatible and appropriate for its intended use.

CONCLUSION:

The performance testing, (e.g., Interface Leak Test, Tensile Strength Test, Consecutive Delivery of Hemostatic Agent Test), summarized in Table 4, support that the EASYGRIP FLO-41 Precision MIS Delivery System performs comparably to the predicate device. Additional supporting data, such as the biocompatibility testing, demonstrate the safety of the EASYGRIP FLO-41 Precision MIS Delivery System. The performance and safety data support that the EASYGRIP FLO-41 Precision MIS Delivery System does not raise different questions of safety and effectiveness and is substantially equivalent to the predicate device that is currently marketed for the same intended use.