December 21, 2020

Advanced Medical Systems Group SRL
Francesco Sgarbi
R&D Manager
Via Europa 12
35020
San Pietro Viminario, Padova
Italy

Re: K201113
Trade/Device Name: Resascope RS-01/B
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: November 18, 2020
Received: November 25, 2020

Dear Francesco Sgarbi:

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/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,

for

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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)*

K201113

Device Name
Resascope RS-01/B

Indications for Use *(Describe)*

When used with a fibreoptic endoscope, Resascope is a video guided catheter intended to be used in the lumbar and sacral spine for observing epidural anatomy, pathology and delivery of drugs approved for epidural indications

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.

510(k) Summary

Applicant:

Company Name:	Advanced Medical Systems Group SRL
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Date Summary Prepared: November 18, 2020

DEVICE IDENTIFICATION

Trade name:	Resascope RS-01/B
Generic/ Common Name:	Video guided catheter
Classification:	21 CFR§ 888.1100, Class II Class II
Classification name:	Arthroscope
Product Code:	HRX
Panel:	Orthopedic

PREDICATE DEVICE:

Myelotec video guided catheter, Myelotec Inc, K980734

DEVICE DESCRIPTION

The Resascope video guided catheter can be used in the lumbar and sacral epidural space to view the epidural anatomy, the pathology and to deliver approved drugs for epidural administration.
It can also be used by physicians to light and view the tissues in the epidural space of the lumbar and sacral spine, and in order to assist in the diagnosis of related pathologies, using a percutaneous approach through the sacral hiatus.
It is designed to be used by trained medical staff for less than 60 minutes usage time period.
It is design with a soft tip and the addition of some blocks inside the handle that allow the catheter to remain locked and therefore oriented, without return to zero.
The medical device is basically structured by two parts: the orientable catheter, intended to enter the peridural space, and the knob, to be used for the orientation of the catheter tip (tip flexion); on the knob there are connection tubes for inserting the endoscope and for connection to the infusion sets.

INDICATIONS FOR USE

When used with a fibreoptic endoscope, Resascope is a video guided catheter intended to be used in the lumbar and sacral spine for observing epidural anatomy, pathology and delivery of drugs approved for epidural indications.

DISCUSSION OF NON-CLINICAL TESTS

Non-clinical tests were conducted to demonstrate substantial equivalence to the predicate device. The test results demonstrated that the proposed device complies with the applicable sections of the standards listed below:

Biocompatibility

The materials used to manufacture the subject device are largely used for other legally marketed devices under the same product code as the submitted Resascope RS-01/B.
Biocompatibility has been tested according to the requirements of
ISO 10993-1:2018, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing.
The following biocompatibility tests were performed:
- Cytotoxicity, ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- Sensitization and Intracutaneous reactivity, ISO 10993-10: 2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization,
- Acute Systemic Toxicity, ISO 10993-11:2006 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
- Haemolysis, ISO 10993-4:2017 Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood, ASTM F756-17, Standard practice for assessment of hemolytic properties of materials, ASTM F-619-14, Standard Practice for Extraction of Medical Plastic.
- Hemocompatibility, ISO 10993-4:2017 Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood, ASTM F2888-19, Standard Practice for Platelet Leukocyte Count - An *In-Vitro* Measure for Hemocompatibility Assessment of Cardiovascular Materials, ASTM F2382-18, Standard Test Method for Assessment of Intravascular Medical Device Materials on Partial Thromboplastin Time (PTT).

Sterilization Validation

A sterilization validation process was performed on the subject device according to
Recognized Consensus Standard: ISO 11135:2014, Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices,
ISO 11138-1: 2017, Sterilization of health care products -- Biological indicators – Part 1: General requirements;
ISO 10993-7 :2008, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals;
ISO 11737-2 :2009, Sterilization of medical devices -- Microbiological methods– Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.

The method used to make the determination of non pyrogenicity was Bacterials Endotoxines by LAL test and Rabbit pyrogen test.
LAL test was performed according to:
- LAL test/USP chapter <85> Bacterial Endotoxins Test,
- ANSI/AAMI ST72 Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing,
- European Pharmacopoeia current edition: 2.6.14 Bacterial Endotoxins.

Pyrogen Test was performed in compliance with:
- ISO 10993-1:2018 “Biological Evaluation of Medical Devices - Part1: Evaluation and Testing within a Risk Management Process
- ISO 10993-2:2006 “Biological Evaluation of Medical Devices - Part 2: Animal welfare requirements”
- ISO 10993-11 “Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity”
- ISO 10993-12:2012 “Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials”.
- U.S. Pharmacopoeia, 2011 USPC Official and General Chapters: <151> Pyrogen test.

Benching tests

The performances of the Resoscope video guided catheter are tested as follows:

Tensile Test to verify the tensile of the shaft welded joints and strain relief bond

Bend Test to verify the proper functioning of the Resascope wheels control

Leak Test to verify there is no leakage in the device

Lock Test to verify the locking mechanism operates correctly

SUBSTANTIAL EQUIVALENCE

The Resacope RS-01/B is same or similar in intended use, design and operating principles to the predicate device (K980734).

Both the subject and the predicate device are indicated for use in clinical environments.
Both the devices have the same principle of operation, same overall design; the same method of use and limited duration of contact with the patient; similar sizes of the catheter.

The minor differences in design do not raise any new types of safety or effectiveness questions. Performance data (design verification testing) demonstrate that the subject device is as safe and effective as the cited predicate.

In further support of a substantial equivalence determination, hereunder is a comparison chart with the submitted device and the predicate device.

SPECIFICATIONS & CHARACTERISTICS			
	Subject device	**K980734**	
Manufacturer	Advanced Medical Systems Group SRL	Myelotec Inc	
Device Name	Resascope RS-01/B	Myelotec video guided catheter	
Common name	Video guided catheter	Video guided catheter	same
Indications For Use	When used with a fibreoptic endoscope, Resascope is a video guided catheter intended to be used in the lumbar and sacral spine for observing epidural anatomy, pathology and delivery of drugs approved for epidural indications.	When used with a fibreoptic endoscope, this device can be used in the lumbar and sacral spine for observing epidural anatomy, pathology and delivery of drugs approved for epidural indications	same
Type of use	Prescription Use (Part 21 CFR 801 Subpart D)	Prescription Use (Part 21 CFR 801 Subpart D)	same
Product Code	HRX	HRX	same
Classification	21 CFR 888.1100 Arthroscope	21 CFR 888.1100 Arthroscope	same

Intended User	The device is to be used by trained personnel only	The device is to be used by trained personnel only	same
Intended Environment	Medical centers	Hospital/surgery center	substantially equivalent
Sterile	yes	yes	same
Single use	yes	yes	same
Design	two parts: the orientable catheter intended to enter the peridural space and the knob for the orientation of the catheter, connection tubes on the knob for visualization through endoscope and for connection to the infusion sets, soft tip, radiopaque distal tip, steel wires in the catheter body render it visible in X-rays	two parts: the orientable catheter intended to enter the peridural space and the knob for the orientation of the catheter, connection tubes on the knob for visualization through endoscope and for connection to the infusion sets, soft tip, radiopaque shaft	substantially equivalent
Insertion point	Sacral Hiatus	Sacral Hiatus	same
Infusion port	2	2	same
Catheter Length	30 cm	30 cm	same
Catheter Outer diameter	from 3.3 mm to 3.5 mm	2.7 mm, 3.0 mm	Substantially equivalent. The difference in the size does not impact safety or effectiveness considering that it is a slight difference also in respect of the mean diameter of the insertion point (sacral hiatus) and the adjacent sacral canal
Lumen inner diameter	1.29 mm	1 mm, 1.3 mm	Substantially equivalent, the size of the lumen inner diameter of the subject device is comprised in the sizes of those of the subject device
Number of lumens for optics and micro instruments	2	2	same

for surgical treatments			
Endoscope capable	yes	yes	same
Steerable	yes	yes	same
Catheter tube Materials	Polyether - Poliammide + Barium Sulfate	not available	The materials used for the components of the device that come in contact with the patient are largely used for medical devices and they have a long history of safe use for the same or equivalent indications. The testing performed on the subject device demonstrate that no issues of safety and effectiveness arise.
Biocompatibility	Meet requirements for ISO 10993-1	not available	

SUBSTANTIAL EQUIVALENCE DISCUSSION:

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Both the medical devices are basically structured by two parts: the adjustable catheter, intended to enter the peridural space, and the knob, to be used for the orientation of the catheter tip; on the handle of both devices there are connection tubes for inserting the endoscope and for connection to the infusion sets.

The subject and predicate devices are based on the same or similar technological elements and are made with the materials largely used for the same type of medical devices already on the market.
The minor differences in the technological characteristics of the devices do not impact the safety and effectiveness of the subject device. The performance data (design verification testing) demonstrate that the subject device is as safe and effective as the cited predicate.

AMS Group believes that the submitted Resascope is substantially equivalent in its intended use, design, materials, function and biocompatibility to the currently cleared device and is therefore as safe and effective.

CONCLUSION:

Based on the available information, we conclude that the Resascope RS-01/B is substantially equivalent to the existing legally marketed device under Federal Food, Drug and Cosmetic Act. Therefore, the subject device is determined to be equivalent to the predicate device.