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

September 26, 2016

Baylis Medical Company, Inc.
Ms. Meghal Khakhar
Director, Regulatory and Scientific Affairs
2645 Matheson Blvd., East
Mississauga, Ontario, Canada L4W 5S4

Re: K161878
Trade/Device Name: PORTAGE System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: August 12, 2016
Received: August 15, 2016

Dear Ms. Khakhar:

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 Part 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 Parts 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,

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)*
K161878

Device Name
PORTAGE™ System

Indications for Use *(Describe)*
The PORTAGE System is indicated for visualization of the surgical field in any area of the body cut open during a surgical procedure. When used in the cervical, thoracic, or lumbar spine either from an anterior or posterior direction, for example, the PORTAGE Endoscope and accessories are intended to aid the surgeon's visualization of the surgical area and allow him/her to perform any type of surgical spinal procedure such as herniated disc repair, visualization of the circumferential decompression of the nerve roots, aiding in the search and removal of nucleus material, spinal fusion, or insertion of spinal implants. Other examples of generic surgical use of the PORTAGE System would be for use in the knee, ankle, shoulder, hand, wrist, and temporomandibular joint (TMJ).

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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7. 510(k) Summary (K161878)

Submitter Information

A. *Company Name*: Baylis Medical Company Inc.

B. *Company Address*: 2645 Matheson Blvd. East
Mississauga, Ontario L4W 5S4
Canada

C. *Company Phone*: (905) 602-4875

D. *Company Facsimile*: (905) 602-5671

E. *Contact Person*: Meghal Khakhar, Director of Regulatory & Scientific Affairs

F. *Summary Prepared on*: 07-Jul-2016

Device Identification

A. *Device Trade Name*: PORTAGE™ System

B. *Device Common Name*: Arthroscope

C. *Classification Name*: CFR 888.1100 - Arthroscope

D. *Product Code*: HRX

E. *Device Class*: Class II

Identification of Predicate Device

Trade Name	Manufacturer	510(k)
METRx System	Medtronic Sofamor Danek	K002931

Indications for Use

The PORTAGE System is indicated for visualization of the surgical field in any area of the body cut open during a surgical procedure. When used in the cervical, thoracic, or lumbar spine either from an anterior or posterior direction, for example, the PORTAGE Endoscope and accessories are intended to aid the surgeon's visualization of the surgical area and allow him/her to perform any type of surgical spinal procedure such as herniated disc repair,

visualization of the circumferential decompression of the nerve roots, aiding in the search and removal of nucleus material, spinal fusion, or insertion of spinal implants. Other examples of generic surgical use of the PORTAGE System would be for use in the knee, ankle, shoulder, hand, wrist, and temporomandibular joint (TMJ).

Device Description

The PORTAGE System is comprised of an endoscope and manual athroscopic instruments.

The PORTAGE Endoscope is a reusable rigid endoscope, comprised of a fiber optic cable and sensitive image transmission system with eyepiece. The PORTAGE Endoscope is used for visualization of the surgical field during arthroscopic or spinal procedures and may be used in conjunction with a separately cleared and commercially available light guide, light source, video camera, monitor and printer. Light that is created by the external light source is transmitted from the PORTAGE Endoscope light guide connector through the endoscope itself to the tip via a fiber optic system. Images are transferred the other way back through a rigid rod lens system. The subject endoscope is manufactured in a 90° short configuration and is used with a compatible bracket. The PORTAGE Endoscope is supplied non-sterile.

The PORTAGE System accessories are manual instruments that include retractors, dilators, rongeurs, forceps, suture passers, cutters, pushers, probes, curettes and gouges. They enable the physician to perform any type of surgical spinal procedure. The manual instruments are either single-use and supplied sterile, or reusable and supplied non-sterile.

The reusable PORTAGE System components have undergone complete reprocessing validations, including manual cleaning and steam sterilization.

Comparison to Predicate Device

The indications for use of the PORTAGE System are identical to that of the predicate METRx System (K002931). The subject and predicate devices also share the same fundamental technology and key device characteristics, including principles of light and image transmission and connection to external components. Like the predicate METRx System, the PORTAGE Endoscope is manufactured in a 90° short configuration and used in conjunction with an endoscope bracket (**Table 7.1**). Differences in design and technological characteristics between the subject and predicate devices do not raise any new types of questions of safety and effectiveness. The results of verification and validation testing provide reasonable assurance of substantial equivalence of the PORTAGE System to its predicate device.

Table 7.1: Comparison of Subject and Predicate Devices

Characteristic	Subject Device Compared to Predicate METRx System (K002931)
Intended Use	Identical
Indications for Use	Identical
Fundamental scientific technology	Identical
Operating principles	Identical
Mechanism of action	Identical
Technological aspects	Similar
System components	Similar

Performance Testing

Performance testing has been completed for the PORTAGE System to demonstrate substantial equivalence to the predicate METRx System (K002931). As applicable, the system components have been subjected to the following verification and validation testing: general performance including endoscope field and direction of view, diopters, eccentricity, size of view, and vignetting, biocompatibility, system compatibility and usability. All test requirements were met as specified by applicable standards and the test protocols.

Conclusions

The subject PORTAGE System and predicate METRx System (K002931) share the same intended use and indications for use. Furthermore, the subject and predicate devices share the same fundamental technology and key device characteristics.

The results of verification testing demonstrate that the subject device meets its predetermined design criteria with respect to general performance aspects, including endoscope field and direction of view, diopters, eccentricity, size of view, and vignetting and biocompatibility requirements. The results of bench top validation testing demonstrate that the PORTAGE System specifications adequately meet user needs and intended uses and usability requirements. Differences in design and technological characteristics between the subject and predicate devices do not raise any new questions of safety and effectiveness. The results of testing demonstrate the subject device is as safe and effective as the predicate METRx System (K002931) when used for its intended purpose and provide reasonable assurance of the substantial equivalence of the subject device to the predicate device.