



Food and Drug Administration
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AB Medica s.a.s
Alexandre Blanc
Chief Executive Officer
Les Petites Quarterees
Mary-Su-Cher 18100
France

September 4, 2015

Re: K151822

Trade/Device Name: ab medica irrigation/suction gravity system
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: February 27, 2015
Received: July 6, 2015

Dear Mr. Blanc:

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" (21CFR 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,

Joshua C. Nipper -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

Indications for Use

510(k) Number (if known)

K151822

Device Name

abmedica Irrigation/Suction Gravity System

Indications for Use (Describe)

ab medica Irrigation/Suction Gravity System is indicated for use in gynecological laparoscopy, laparoscopic cholecystectomy and other laparoscopic procedures.

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 K151822

510(k) SUMMARY OF SAFETY & EFFECTIVENESS
(Content in accordance with 21 CFR §807.92)

510(k) No: K151822

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Date Prepared: August 25, 2015

Trade Name: ab medica irrigation / suction gravity system

Common Name: Laparoscopic suction / irrigation system

Classification Name: Endoscope and accessories under 21 C.F.R. 876.1500

Regulatory Class: II

Product Code: GCJ

Predicate Devices: CORE DYNAMICS, INC., Laparoscopic/suction/irrigation probe (K935826)
CORE DYNAMICS, INC., Suction/irrigation "Y" tubing set w/trumpet valves (K930512)

Device Description: ab medica Irrigation/Suction Gravity System is intended for irrigation and suctioning of the surgical field during laparoscopic surgery. This device is intended to be used in the operating room and by surgeons only.
The system consists of control handpiece pre-connected to a tubing set and removable cannula. The tubing set and the 5 mm and 10 mm



cannulae are single-use devices and provided in sterile condition. Only the 3 mm reusable cannula is provided non sterile. The system is used during laparoscopic surgery to deliver sterile irrigation fluids and/or to produce suction to evacuate blood and small tissue debris, and to maintain a clear view of the surgical site. Irrigation and suctioning functions are provided through the cannula, which is inserted to the surgical site by means of a trocar, and are manually controlled by surgeon through the control valves on the handpiece.

Single-use tubing sets and cannulae are provided sterile .ETO sterility validation has been performed ISO 11135-1, Sterilization of health care products –Ethylene Oxide – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices; and ISO 10993-7, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals. A sterility assurance level (SAL) of 10^{-6} is achieved.

The shelf life of single use devices was verified in accordance with *ISO 11607-1 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems* and *ISO 11607-2 Packaging for terminally sterilized medical devices: Part 2: Validation requirements for forming, sealing and assembly processes*.

The reusable cannula is provided non-sterile and must be cleaned, disinfected, and sterilized by moist heat before each use. Cleaning validation was performed in accordance with AAMI *TIR12* and AAMI *TIR30*. Sterility validation was performed in accordance with *ISO 17665-1: Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*, .to an SAL of 10^{-6} .

Intended use:

abmedica Irrigation/Suction Gravity System is intended for irrigation and suctioning of the surgical field during laparoscopic surgery. This device is intended to be used in the operating room and by surgeons only.

Indications for use:

abmedica Irrigation/Suction Gravity System is indicated for use in gynecological laparoscopy, laparoscopic cholecystectomy and other laparoscopic procedures.

Substantial Equivalence:

abmedica irrigation/suction gravity system has the same intended use, general design and principle of functioning than the predicate. Both subject and predicate systems deliver sterile lavage solution and evacuate fluids, including blood and small tissue debris, to maintain a



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clear view of the surgical site.

They are both composed of twin tubing set, control handpiece and cannula. Irrigation/ suction to / from the operative site are provided through the cannula.

Non-clinical simulated use testing was performed to verify safety and effectiveness as compared to the predicate.

Performance testing, including irrigation and suction flow rate, verified that the abmedica irrigation/suction gravity system is substantially equivalent to the predicate Core Dynamics devices and raises no new issues of safety and effectiveness.

Based on the intended use, technical characteristics and performance data, abmedica irrigation/suction gravity system is equivalent to the predicate device in terms of safety, effectiveness, and performance. Therefore, it is considered substantially equivalent to predicate.