

K072383¹⁰⁽²⁾

SECTION 3
Summary of Safety and Effectiveness

Sponsor: EMcision, Ltd.

Contact Person: Nagy Habib, MD
Chief Executive Officer
Liver Surgery Section, Hammersmith Hospital
Du Cane Road
London, W12 0NN
United Kingdom

NOV 29 2007

Summary Prepared: 2007-05-01

Trade Name: Habib Endoblate

Common Name: Endoscopic Electrosurgical Unit

Classification: ~~Class II~~ per 21 CFR 878.4400

Product Code: Gastroenterology-Urology (GU)
Gastro-Renal (GRDB)
GEI

Predicate Devices: Gold Probe catheter manufactured by Boston Scientific Inc. (K970278)

Intended Use:

The Habib Endoblate is a radiofrequency (RF) catheter which provides bipolar energy to enable the Endoscopist to cauterize and coagulate tissue in the gastrointestinal tract

Description:

The Habib Endoblate is a bipolar radiofrequency (RF) device that consists of a catheter with 3 contact electrodes and 1 ring electrode, introduced via an endoscope's biopsy channel and activated with bipolar RF energy.

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The Habib Endoblate has an attached cable which connects the device to an RF Generator. The catheter is inserted into the gastrointestinal tract and the tissue is coagulated using the RF power. The Habib Endoblate is designed for use in endoscopy and is a single use sterile device.

Technological Differences:

The Habib Endoblate has the same basic technological characteristics as the Gold Probe. Both devices use bipolar RF energy through a number of electrodes to coagulate tissue.

Performance Data:

Performance testing was undertaken to ensure that the Habib Endoblate functions as intended and meets design specifications. Sufficient data was obtained to show that the device is substantially equivalent to the predicate device and meets safety and effectiveness criteria.



NOV 29 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Emcision Ltd.
c/o Morten Simon Christensen
Staff Engineer & FDA Office Coordinator
Underwriters Laboratories, Inc.
455 E. Trimble Road
SAN JOSE CA 95131-1230

Re: K072383
Trade/Device Name: Habib Endoblate
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KNS
Dated: November 8, 2007
Received: November 13, 2007

Dear Mr. Christensen:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

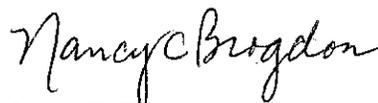
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 2
Indications for Use Statement

Indications For Use Statement

510(K) Number (if known) Not yet Allocated

Device Name Habib Endoblate

The Habib Endoblate is a radiofrequency (RF) catheter which provides bipolar energy to enable the Endoscopist to cauterize and coagulate tissue in the gastrointestinal tract

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K07 2383

Prescription Use OR Over the Counter Use

(per 21 CFR 878.4400)