K022979 p1of2

DEC 1 8 2002

510(k) Summary Instruments Médicaux G.B. Inc.
(LAPARETTE) *(per 21 CFR 807. 92)*

1. DATE of PREPARATION: August 22, 2002

2. SPONSOR/APPLICANT: Instruments Médicaux G.B. Inc. 425, des Jonquilles street
Sherbrooke, Quebec, Canada, J 1 E 2Z9

3. CONTACT NAME: Germain Béland Telephone 819-566-5689

4. DEVICE NAME: LAPARETTE

5. IDENTIFICATION OF THE PREDICATE OR LEGALLY MARKETED DEVICES) TO WHICH EQUIVALENCE IS BEING CLAIMED:

Laparette (K971146)
RD CHUS, Inc.

6. DEVICE DESCRIPTION:

INTENDED USE: The LAPARETTE is intended for use in minimally invasive surgery, including laparoscopy, to cut tissue and control bleeding by use of high-frequency electrical current, irrigate tissue and cavities, as well as suction fluids from the wound. This device is not intended for use in tubal sterilisation procedures.

OVERVIEW: The LAPARETTE is a hybrid device consisting of three reusable component (Protective sheath, Electrode-Cannula, and Insulated Sleeve) and one single use component(Cartridge and Handle all together). All LAPARETTE components are supplied non sterile, requiring sterilization by health care facility before first use and reuse of the reusable components. The LAPARETTE is sold as a set. The only option possible for the customer is the form of the cautery tip.

7. BASIS FOR SUBSTANTIAL EQUIVALENCE: Instruments médicaux G.B. Inc. makes the claim of substantial equivalence to the above devices based on intended use, design considerations, and general operating characteristics. Also, the LAPARETTE of Instruments Médicaux G.B. inc. is exactly the same because the patent and ownership has been transfer from RD CHUS inc. to Instruments Médicaux G.B. Inc.

All two devices share the same intended use of electrocautery, irrigation, and suction using the same instrument. All two products are designated for monopolar use only. While the RD CHUS LAPARETTE was sold non sterile, Instruments Médicaux G.B. Inc. will sell it non sterile but nine time reusable. The recommended sterilization technique for the LAPARETTE is ethylene oxide sterilization. The RD CHUS LAPARETTE has the possibilities to be sold separately from the accessories, the LAPARETTE from

Instruments Médicaux G.B. Inc. only give the option to the customer to choose the tip form.

To be able to have a nine time reusable devices, Instruments Médicaux G.B. Inc. include nine separate single use non sterile handle..

Martin Paquette
Official Correspondent of Instruments Médicaux G.B. Inc.

August 22, 2002
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2002

Instruments médicaux G. B., Inc.
c/o Mr. Martin Paquette
Official Correspondent
Groupe Horzone
1184 Blvd. Alexandre
Sherbrooke, Quebec
CANADA

Re: K022979
Trade/Device Name: Laparette, Model Lap J, L, S, H, & N
Regulation Number: 21 CFR §884.4160
Regulation Name: Unipolar endoscopic coagulator-cutter and accessories
Regulatory Class: II
Product Code: 85 KNF
Dated: November 4, 2002
Received: November 18, 2002

Dear Mr. Paquette:

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 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 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

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

Enclosure

Instruments médicaux G.B.

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: Instruments Médicaux G.B. inc.

510(K) Number (if known): K022979

Device Name: Laparette

Indications For Use:

The LAPARETTE is an electrosurgical instrument with integral suction and irrigation capability. It is intended for use in minimally invasive surgery, including laparoscopy, to cut tissue and control bleeding by use of high frequency electrical current, to irrigate tissue and cavities, as well as to suction fluids from the wound. This device is not intended for use in tubal sterilization procedures.

Martin Paquette
Official Correspondent

August 22, 2002
Date

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022979

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