K971146

510(k) Summary
RD CHUS, Inc. LAPARETTE
(per 21 CFR 807.92)

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AUG 25 1997

1. **DATE OF PREPARATION:** March 27, 1997

2. **SPONSOR/APPLICANT:** RD CHUS Inc.
3001, 12th ave North,
Fleurimont, Quebec, Canada, J1H 5N4

3. **CONTACT NAME:** Fernand Jalbert
Telephone: 819-563-5555 Ext. 14252

4. **DEVICE NAME:**

Trade/Proprietary Name:	LAPARETTE
Common/Usual Name:	Electrosurgical electrode, suction, irrigation
Classification Name:	Accessory to electrosurgical cutting and coagulation device or laparoscopic accessory

5. **IDENTIFICATION OF THE PREDICATE OR LEGALLY MARKETED DEVICE(S) TO WHICH EQUIVALENCE IS BEING CLAIMED:**

Davis+Geck's Multi-Function Pistol Grip (K921696)
American Cyanamid Co.

Ethicon Endopath Probe Plus (K912492)
Ethicon, 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 sterilization procedures.

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OVERVIEW: The LAPARETTE is a hybrid device consisting of three reusable (Handle, Electrode-Cannula, and Insulated Sleeve) and two single use components (Cartridge and Sheath). All LAPARETTE components are supplied non-sterile, requiring sterilization by the health care facility before use. The LAPARETTE is sold both as a set and as individual products. Bench and animal testing provided in the 510(k) was used to characterize the performance of the LAPARETTE.

7. **BASIS FOR SUBSTANTIAL EQUIVALENCE:** RD CHUS Inc. makes the claim of substantial equivalence to the above devices based on intended use, design considerations, and general operating characteristics. All three devices share the same intended use of electrocautery, irrigation, and suction using the same instrument. All three products are designated for monopolar use only. While the D&G Multi-Function and Ethicon Probe Plus are single use only, the LAPARETTE is a hybrid of reusable and single use devices. The recommended sterilization technique for the LAPARETTE is steam for all but the Protective Sheath which requires ethylene oxide sterilization. Although the specific materials of construction are different, all cited devices use polymers common to various medical devices. All three products use a pistol grip handle design. The LAPARETTE uses a separate disposable cartridge, while that function is integral to the handles of the D&G Multi-Function and Ethicon Probe Plus. The LAPARETTE and the D&G Multi-Function share the feature of tip rotation, while the Ethicon Probe Plus requires that the entire device is rotated. While the LAPARETTE and the Ethicon Probe Plus feature the ability to shield the tip during insertion into the wound by providing the ability to retract the sheath over the exposed tip, the D&G Multi-Function does not allow retraction. The dimensions of all three devices are similar with usable shaft lengths of 30.5 mm for the LAPARETTE, 31.75 mm for the D&G Multi-Function, and 35 mm for the Ethicon Probe Plus. Shaft O.D.s range from 5.0 mm to 5.4 mm. Devices are compatible with trocar sizes of 5.5 (LAPARETTE) and 5.0 for the other devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 1997

RD CHUS, Inc.
c/o Rosina Robinson, R.N., RAC
Medical Device Consultants, Inc.
Staff Consultant
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K971146
Laparette
Dated: July 9, 1997
Received: July 10, 1997
Regulatory class: II
21 CFR §884.4160/Product code: 85 KNF

Dear Ms. Robinson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

William Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): New 510(k) K971146

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.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Rathing

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971146

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)