SECTION 10

510(k) Summary

JUN 29 2009

Submitter:

NOUVAG AG
St. Gallerstrasse 23-25
CH-9403 Goldach
Switzerland

Contact Person:

Erich Forster (INTRATest GmbH)
Consultant
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Date Summary Prepared: June 25, 2009

Device Name:

Proprietary Name: Morce Power Plus Morcellator (Distributed by Richard Wolf)
VarioCarve Morcellator (Distributed by Olympus)

Common Name: Morcellator

Classification Name: Gynecologic laparoscope and accessories
(per 21 CFR section 884.1720)

Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

ETHICON, Inc.
GYNECARE X-TRACT Tissue Morcellator
K993801, Cleared on 02/07/2000

WISAP Gesellschaft für wissenschaftl. App.bau
S*E*E*M SET
K960640, cleared on 02/14/1997

WISAP Gesellschaft für wissenschaftl. App.bau
POWER-DRIVE,WISAP Model 7688PD/7688PD1
K982515, cleared on 01/19/1999

Device Description:

The Morce Power Plus / VarioCarve is the drive control unit for the morcellator. With a cutting blade on the distal end, a rotating cylindrical tube is inserted in the abdominal cavity.

Sterility:
Motor, motorcable, and morcellator: Sterility by user up to 134°C.

Intended use of the Devices:

Morce Power Plus Morcellator (Distributed by Richard Wolf)
The Morce Power Plus morcellator is intended for use in operative laparoscopy, including laparoscopic general surgical procedures and laparoscopic gynecological procedures to morcellate and remove tissue.

VarioCarve Morcellator (Distributed by Olympus)
The VarioCarve morcellator is intended for morcellating and extracting tissue (e.g. removing myomata or the uterus) during laparoscopic procedures in general surgery and gynecology.

Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device:

The Morcellator is substantially equivalent to other legally marketed devices in the United States. The Morcellator functions in a manner similar and are intended for the same use as the Devices designed by Ethicon, Inc. and WISAP Gesellschaft für wissenschaftl. App.bau

Brief summary of nonclinical tests and results:

The Morcellator has been designed and tested to applicable safety standards. The Morcellator does not raise any new issues of safety, effectiveness, or performance of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2009

Nouvag AG
c/o Mr. Erich Forster
INTRATest Systems GmbH
Reusswehrstrasse 1
Gebenstorf
SWITZERLAND CH-5412

Re: K080365
Trade/Device Name: Morce Power Plus Morcellator (Distributed by Richard Wolf)
VarioCarve Morcellator (Distributed by Olympus)
Regulation Number: 21 CFR §884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: II
Product Code: HET
Dated: June 8, 2009
Received: June 16, 2009

Dear Mr. Forster:

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); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080365

Device Name: Morce Power Plus Morcellator (Distributed by Richard Wolf)

Indications For Use:

The Morce Power Plus morcellator is intended for use in operative laparoscopy, including laparoscopic general surgical procedures and laparoscopic gynecological procedures to morcellate and remove tissue.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT 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 K080365

Indications for Use

510(k) Number (if known): K080365

Device Name: VarioCarve Morcellator (Distributed by Olympus)

Indications For Use:

The VarioCarve morcellator is intended for morcellating and extracting tissue (e.g. removing myomata or the uterus) during laparoscopic procedures in general surgery and gynecology.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT 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 K080365