SEP 1 1 2009

K091223

510(k) Summary or 510(k) Statement

510(k) Summary

1. Submitter Information:

Covidien LP
Formerly known as Valleylab, a Division of Tyco Healthcare Group LP
5920 Longbow Drive
Boulder, CO
Contact: Philip E. Ake
Senior Regulatory Associate
Phone: 303-581-6934
Fax: 303-516-8516
Email: Philip.Ake@Covidien.com

2. Name of Device

Trade name: Valleylab Suction Coagulators
Common/Classification name: Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)

3. Predicate Devices

The Valleylab Suction Coagulators are substantially equivalent to the following legally marketed medical devices:

- Valleylab Lectrovac (K791752)
- Megadyne Suction Coagulator (K072559)

4. Device Description

The Valleylab Suction Coagulators are hand held electrosurgical devices used for the coagulation of tissue and aspiration of fluids during electrosurgical procedures. The devices are activated by a plastic button with a spring contact located in the handle of the device. The suction is activated by the surgeon placing a finger over the suction vent hole also in the handle.

5. Intended Use

The Suction Coagulator is a single use device intended for use in surgical procedures (such as general and ENT procedures) where the coagulation of tissue and suction of fluids are desired.

6. Summary of Technology Characteristics

The Suction Coagulators are a disposable, hand held device used in electrosurgical procedures. It provides control of both monopolar coagulation of tissue and suction of fluids in a single handle. The coagulation mode of operation is activated by a depressing a plastic button located on the top of the body. The activation of suction is activated by the surgeon's finger covering the suction port. Coagulation takes place at the uninsulated end of the suction tube. The Suction coagulator consists of four main elements:

-a metal, insulated, French sized tube
-a switching mechanism
-a two piece molded plastic body
-a cord with plug

The Suction Coagulator is supplied sterile and can be used with various electrosurgical generators.

7. Summary Non-clinical testing

Bench Testing and verification testing was conducted to ensure proper device function. This included testing to the relevant electrical standards (IEC 60601-1 and IEC 60601-2-2).

8. Summary of Clinical testing

No clinical testing was conducted. The use of Electrosurgical Suction Coagulators has been documented in the published literature and indicates safe and effective use in ENT procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 11 2009

Covidien LP
% Mr. Philip E. Ake
Senior Regulatory Associate
5920 Longbow Drive
Boulder, Colorado 80301

Re: K091223
Trade Name: Suction Coagulator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 27, 2009
Received: July 29, 2009

Dear Mr. Ake:

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): __K091223_____

Device Name: Suction Coagulator

Indications for Use:

The Suction Coagulator is a single use device intended for use in surgical procedures (such as general and ENT procedures) where the coagulation of tissue and suction of fluids are desired.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091223