AUG 3 1 2001

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: TBD K012317

Applicant Information:

Date Prepared: July 16, 2001

Name: Coalescent Surgical, Inc.
Address: 559 E. Weddell Drive
Sunnyvale, CA 94089
408-743-9794

Contact Person: Michael A. Daniel
Phone Number: (415) 407-0223
Facsimile Number: (925) 932-5706

Device Information:

Classification: Class II Implantable Clips
Trade Name: Coalescent Surgical U-Clip™
Common Name: Implantable Clip, Vascular Clip
Classification Name: Surgical Devices: Implantable Clip, 79FZP, 21 CFR 878.4300

Predicate Devices:

The Coalescent Surgical U-Clip™ is substantially equivalent in intended use and method of operation to the following predicate devices:

- Coalescent Surgical Sutured-Clip™ - 510(k) K994160

Device Description:

The Coalescent Surgical U-Clip™ is a single self-closing clip for vascular anastomosis and tissue approximation applications. The U-Clip consists of a specially designed vascular clip with a needle connected to one end via a flexible member. This design allows precise placement of clips prior to closure. The device is fabricated from standard medical and implantable grade materials.

510(k) SUMMARY

(Continued)

Intended Use:

The Coalescent Surgical U-Clip™ is intended for endoscopic and non-endoscopic use in tissue and prosthetic material approximation and the creation of anastomoses in blood vessels, grafts and other tubular structures.

Comparison to Predicate Device(s):

The Coalescent Surgical U-Clip™ is substantially equivalent to the Coalescent Surgical Sutured-Clip (K994160). These devices are intended for application of vascular clips to tissue for purposes of performing vascular anastomosis and tissue and graft approximation.

***In Vitro* Test Data:**

Design analysis and *in vitro* data confirm that functional characteristics are substantially equivalent to the predicate device cited. Testing included *in vitro* studies. All data fell well within, both, internal specification requirements, as well as external standard requirements and predicate performance expectations.

Summary:

Based upon the product technical information, intended use, performance and biocompatibility information provided in this pre-market notification, the Coalescent Surgical U-Clip™ has been shown to be substantially equivalent to currently marketed predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2001

Mr. Michael A. Daniel
Regulatory and Clinical Affairs
Coalescent Surgical
559 East Weddell Drive
Sunnyvale, California 94089

Re: K012317
Trade/Device Name: Coalescent Surgical U-Clip™
Regulation Number: 878.4300
Regulatory Class: II
Product Code: FZP
Dated: July 16, 2001
Received: July 23, 2001

Dear Mr. Daniel:

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 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). 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 requirements, 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) 594-4659. 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" (21CFR 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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012317

510(k) Number (if known): TBD

Device Name: Coalescent Surgical U-Clip™

Indications For Use:

The Coalescent Surgical U-Clip™ is intended for endoscopic and non-endoscopic use in tissue and prosthetic material approximation and the creation of anastomoses in blood vessels, grafts and other tubular structures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012317