FEB 4 2000

K994160

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

Applicant Information:

Date Prepared: December 1, 1999

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: (408) 743-9798

Device Information:

Classification: Class II Implantable Clips
Trade Name: Coalescent Surgical Sutured-Clip™
Common Name: Implantable Clip, Vascular Clip
Classification Name: Surgical Devices: Implantable Clip, 79FZP, 21 CFR 878.4300
Cardiovascular Prosthetic Devices: Vascular Clip, 74DSS 870.3250

Predicate Devices:

The Coalescent Surgical Sutured-Clip™ is substantially equivalent in intended use and/or method of operation to a combination of the following predicate devices:

1. Elective Vascular Intervention (EVI) Sutured-Clip™ and Clip Applier – 510(k) K971588
2. U.S. Surgical, Auto Suture Modified VCSClip and Applier – 510(k) K962043
3. Ethicon, Endo-Surgery Endoscopic Clip and Applier – 510(k) K771412

Device Description:

The Coalescent Surgical Sutured-Clip™ is a single self-closing clip for vascular anastomosis and tissue approximation applications. The Sutured-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 Sutured-Clip™ is intended for endoscopic and non-endoscopic use in the creation of anastomoses in blood vessels, grafts and other tubular structures.

Comparison to Predicate Device(s):

The Coalescent Surgical Sutured-Clip™ is substantially equivalent to a combination of the EVI Sutured-Clip™ and Sutured-Clip™ Applier and to the US Surgical VCS Clip™ and Clip Applier in terms of intended use. These devices are intended for application of vascular clips to tissue for purposes of performing vascular anastomosis.

The Coalescent Surgical Sutured-Clip™ is substantially equivalent to the EVI Sutured-Clip™ and Sutured-Clip™ Applier in that the Sutured-Clips™ have a needle attached to one end to facilitate precise placement. The Coalescent Surgical Sutured-Clip™ is substantially equivalent to the Ethicon LIGACLIP™ Clip and Clip Applier in terms of the single clip application option.

The Coalescent Surgical, Inc Sutured-Clip™ differs from the currently marketed predicate devices in that it is self-closing and does not require a custom clip applier.

***In Vitro, In Situ* and *In Vivo* Test Data:**

Design analysis, *in vitro*, *in situ* and *in vivo* data confirm that basic functional characteristics are substantially equivalent to the predicate devices cited. Testing included *in vitro, in situ* and chronic *in vivo* 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 Sutured-Clip™ has been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 4 2000

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

Re: K994160
Trade Name: Sutured-Clip
Regulatory Class: II
Product Code: FZP
Dated: December 1, 1999
Received: December 9, 1999

Dear Mr. Daniel:

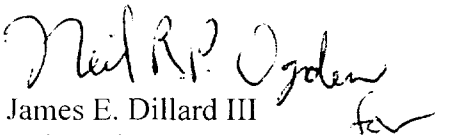
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4595. 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,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~TBD~~ K994160

Device Name: **Coalescent Surgical Sutured-Clip™**

Indications For Use:

The Coalescent Surgical Sutured-Clip™ is intended for endoscopic and non-endoscopic use in 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)

MRO for JSD

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994160

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

(Optional Format 1-2-96)