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K031623
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2.0 510(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: May 21, 2003

Name: Coalescent Surgical, Inc.
Address: 559 E. Weddell Drive
Sunnyvale, CA 94089
408-743-9780

Contact Person: Michael A. Daniel
Phone Number: (415) 407-0223
Facsimile Number: (925) 254-5187

Device Information:

Classification: Class II Implantable Clips / Class II Suture
Trade Name: Coalescent Surgical U-CLIP™ and Accessories
Common Name: Implantable Clip / Vascular Clip / Suture
Classification Name: Surgical Devices: Implantable Clip, 79FZP, 21CFR 878.4300
Suture, 79NJU, 21CFR 878.4495

Predicate Devices:

The Coalescent Surgical U-CLIP™ and accessories is substantially equivalent in intended use, fabrication and design to the following predicate device:

- Coalescent Surgical U-CLIP™ - K024366, K023125, K021407, K013664, K012317, K994160, and K971588

Device Description:

The Coalescent Surgical U-CLIP™ device is a self-closing clip for vascular anastomosis and tissue approximation/attachment applications. The U-CLIP consists of specially designed vascular clips optionally connected to needles via flexible members. These clips may or may not include coils surrounding a Nitinol wire core. This design allows precise placement of clips prior to closure and facilitation of an interrupted "suture" technique through elimination of knot tying. The device is fabricated from standard medical and implantable grade materials. Accessories include Clip delivery and removal devices as well as vessel cutting and retention tools.

510(k) SUMMARY

(Continued)

Intended Use:

The Coalescent Surgical U-CLIP™ is intended for endoscopic and non-endoscopic general soft tissue and prosthetic material approximation/attachment and/or ligation and the creation of anastomoses in blood vessels, grafts and other tubular structures; including use in cardiovascular and coronary artery bypass grafting procedures.

Comparison to Predicate Device(s):

The Coalescent Surgical U-CLIP™ and accessories is substantially equivalent to the Coalescent Surgical U-CLIP K024366, K023125, K021407, K013664, K012317, K994160 and K971588 in terms of materials, use and application.

Test Data:

In vitro and *in vivo* data have confirmed that functional characteristics are substantially equivalent to the predicate device cited as well as applicable USP suture testing requirements. All data fell well within, both, internal specification requirements, as well as external standard requirements and device performance expectations.

Summary:

Based upon the product technical information, intended use, *in vitro*, *in vivo* and clinical performance information provided in previous pre-market notifications, the Coalescent Surgical U-CLIP™ and accessories 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

JUL 3 2003

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

Re: K031623
Trade/Device Name: Coalescent Surgical U-CLIP™ and Accessories
Regulation Number: 21 CFR 878.4300, 21 CFR 878.4495
Regulation Name: Implantable clip, Stainless steel suture
Regulatory Class: II
Product Code: FZP, NCA, NJU
Dated: May 22, 2003
Received: June 4, 2003

Dear Mr. Daniel:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), 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 Part 807.97) you may obtain. 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,

for 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

4.0 INDICATIONS FOR USE FORM

510(k) Number (if known): TBD K031623

Device Name: **Coalescent Surgical U-CLIP™ and Accessories**

Indications For Use:

The Coalescent Surgical U-CLIP™ is intended for endoscopic and non-endoscopic general soft tissue and prosthetic material approximation/attachment and/or ligation and the creation of anastomoses in blood vessels, grafts and other tubular structures; including use in cardiovascular and coronary artery bypass grafting procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

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

510(k) Number K031623

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

(Optional Format 1-2-96)