

2.0 510(k) SUMMARY

DEC 18 2002

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: _____ K023125 _____

Applicant Information:

Date Prepared: December 18, 2002

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: Suture, 79NJU, 21CFR 878.4495
Implantable Clip, 79FZP, 21CFR 278.4300

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™ - K021407, K013664, K012317, K994160 and K971588
- Ethicon Stainless Steel, Gut, Poly suture – K946173 (GAQ)

510(k) SUMMARY

(Continued)**Device Description:**

The Coalescent Surgical U-CLIP™ device is a single self-closing clip for vascular anastomosis and tissue approximation/attachment applications. The U-CLIP consists of a specially designed vascular clip (optionally containing suture) and connected to needles via flexible members (optionally including various types of suture). 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 removal devices and vessel retention tools.

Intended Use:

The Coalescent Surgical U-CLIP™ is indicated for use in general soft tissue approximation and/or ligation, including cardiovascular applications.

Comparison to Predicate Device(s):

The Coalescent Surgical U-CLIP™ and accessories is substantially equivalent to the Coalescent Surgical U-CLIP (K021407) and to Ethicon Stainless Steel, Gut, Poly suture – K946173 (GAQ), in terms of materials, use and application.

Test Data:

In vitro and *in vivo* data confirm 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 this pre-market notification, the Coalescent Surgical U-CLIP™ and accessories has been shown to be substantially equivalent to currently marketed predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 2002

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

Re: K023125

Trade/Device Name: Coalescent Surgical U-CLIP™ and Accessories
Regulation Number: 878.4495
Regulation Name: Stainless steel suture
Regulatory Class: Class II
Product Code: NJU Non-Absorbable nitinal suture
Dated: September 16, 2002
Received: September 19, 2002

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

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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" (21 CFR Part 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,



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

K023125

510(k) Number (if known): TBD

Device Name: Coalescent Surgical U-CLIP™ and Accessories

Indications For Use:

The Coalescent Surgical U-CLIP™ and accessories is indicated for use in general soft tissue approximation and /or ligation, including use in cardiovascular procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

Division Sign-Off

Division of General, Restorative
and Neurological Devices

K023125

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)