

## 2.0 510(k) SUMMARY

JUL 3 2003

K031623  
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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

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(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.



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.

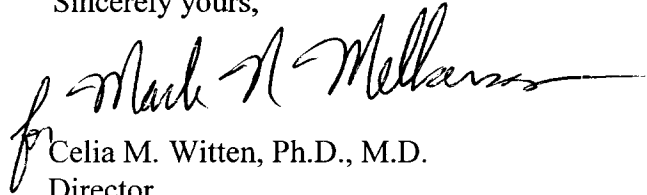
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 - Mr. Michael A. Daniel

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a long horizontal flourish extending to the right.

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

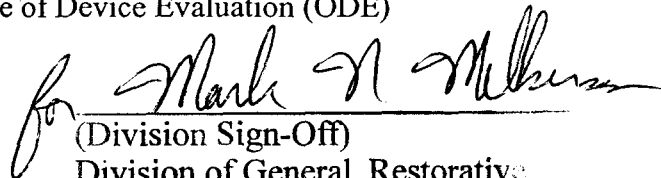
Device Name: Coalescent Surgical U-CLIP™ and Accessories

#### 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)



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

510(k) Number K031623

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)