DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2003

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

Re: K013664
Trade/Device Name: Coalescent Surgical U-CLIP™
Regulation Number: 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NCA
Dated: October 31, 2001
Received: November 6, 2001

Dear Mr. Daniel:

This letter corrects our substantially equivalent letter of January 24, 2002 regarding the Coalescent Surgical U-CLIP™. We are changing the product code from FZP to NCA.

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 (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 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 continue 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 and additionally Part 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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Miriam C. Provost

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

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; including 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)

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

(Optional Format 1-2-96)

for Mark N Milhern
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013664

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.

JAN 2 4 2002

510(k) Number: ~~TBD~~ K013664

Applicant Information:

Date Prepared:	October 31, 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 device:

- Coalescent Surgical U-CLIP™ - 510(k) K012317

Predicate devices intended for tissue approximation and the creation of anastomosis that have been cleared for cardiovascular indications include:

- St. Jude Medical, Symmetry Aortic Clip System – 510(k) K003446
- Ethicon, Polypropylene, PRONOVA Nonabsorbable Suture – 510(k) K001625

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 and facilitation of an interrupted technique. 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; including cardiovascular and coronary artery bypass grafting procedures.

Comparison to Predicate Device(s):

The Coalescent Surgical U-CLIP™ is substantially equivalent to the Coalescent Surgical U-CLIP (K012317). These devices are intended for application of vascular clips to tissue for purposes of performing vascular anastomosis and tissue and graft approximation. The specific cardiovascular indication is substantially equivalent to both the St. Jude Symmetry Clip, K003446 and the Ethicon PRONOVA Nonabsorbable Suture, K001625.

Test Data:

Clinical data confirm that functional characteristics are substantially equivalent to the predicate device cited. 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 and clinical performance information provided in this pre-market notification, the Coalescent Surgical U-CLIP™ has been shown to be substantially equivalent to currently marketed predicate devices.