FEB - 6 2001

K003958

**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: | November 1, 2000 |
| Name: | Coalescent Surgical, Inc. |
| Address: | 559 E. Weddell Drive<br>Sunnyvale, CA 94089<br>408-743-9794 |
| Contact Person: | Michael A. Daniel |
| Phone Number: | (415) 407-0223 |
| Facsimile Number: | (925) 932-5706 |

**Device Information:**

| | |
|---|---|
| Classification: | Class II - Manual Surgical Instrument<br>[Accessory to Class II Coalescent U-Clip™] |
| Trade Name: | Coalescent U-Clip™ Delivery and Disposal Device |
| Common Name: | Delivery and Disposal Device |
| Classification Name: | Instrument, Surgical Disposable 56KDC, 21 CFR 878.4800 AND<br>Instrument, Surgical Non-Powered 57HAO, CFR 882.4535 |

**Predicate Devices:**

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

1. Medcare Products Disposable Needle Holder – 510(k) K831665
2. U.S. Surgical, non-powered re-useable Class I Needle Holder, Surgical Instruments

**Device Description:**

The Coalescent U-Clip™ Delivery and Disposal Device consists of a disposable cartridge that snaps onto a reusable hand piece. The cartridge has two compartments: one compartment holds multiple Single or Double-Arm U-Clips™ and the other compartment collects needle assemblies. See 510K K994160 for detailed descriptions of the U-Clip. The cartridge is preloaded with U-Clip(s), is a single use only, and is packaged separately from the hand piece. The hand piece is a reusable product and consists of an outer tube and an actuator rod. The actuator rod inserted into the outer tube is normally compressed by a compression spring captured at the proximal end of the outer tube and can be slid back and forth by sliding a thumb knob. The device is fabricated from standard medical grade materials.

(Continued)

**Intended Use:**

The Coalescent U-Clip™ Delivery and Disposal Device is intended for endoscopic and non-endoscopic delivery and disposal of Coalescent U-Clips.™

**Comparison to Predicate Device(s):**

The Coalescent U-Clip™ Delivery and Disposal Device is substantially equivalent to a combination of the Medcare Products Disposable Needle Holder – 510(k) K831665 and the U.S. Surgical, non-powered re-useable Class I Needle Holder, Surgical Instruments.

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

Design analysis, *in vitro* and *in situ* data confirm that basic functional characteristics are substantially equivalent to the predicate devices cited. Testing included *in vitro and in situ* 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 U-Clip™ Delivery and Disposal Device 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 - 6 2001

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

Re: K003958
Trade Name: Coalescent U-Clip™ Delivery and Disposal Device
Regulatory Class: II
Product Code: FZP
Dated: December 18, 2000
Received: December 21, 2000

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,

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

K003958

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

**Device Name:** Coalescent U-Clip™ Delivery and Disposal Device

**Indications For Use:**

The Coalescent U-Clip™ Delivery and Disposal Device is intended for endoscopic and non-endoscopic delivery and disposal of Coalescent U-Clips.™

(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 Devices
510(k) Number K063958

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

(Optional Format 1-2-96)