Summary of Safety and Effectiveness

Trade Name:

Coapt Systems ENDOTINE Device ™

DEC 2 0 2002

Manufacturer Information:
Coapt Systems, Inc.
1820 Embarcadero Road
Palo Alto, CA 94303
Phone: 650.331-7680 (Daniel Jacobs, MD)
Site Registration number: 3003644133
e-mail: djacobs@coaptsystems.com

Contact:
Shelley Trimm
1152 Navarro Street
Santa Rosa, CA 95401
Phone: 707.545-7337
FAX: 707.545-7734
e-mail: shelleytrimm@telocity.com

Establishment Registration Number: 3003644133

FDA Device Classification:

Standard Product Nomenclature:	Smooth or Threaded Metallic Bone Fixation Fastener
Product Code:	HWC
CFR Number:	888.3040
Risk Class:	Class II
Classification Panel:	General Restorative & Neurological Devices

Intended Use and Indication for Use:

The ENDOTINE device intended use and indication for use will remain unchanged.

The ENDOTINE device will continue to be intended for use in browplasty surgery.

The ENDOTINE device will continue to be labeled with the indication for use of:

> The ENDOTINE Device is intended for use in browplasty surgery. The ENDOTINE device is specifically intended for use to fixate the sub-dermis to the cranial bone in browplasty procedures.

Product Description:

The ENDOTINE system includes the bioabsorbable ENDOTINE Implant, a stainless steel step drill-bit intended to be used in conjunction with the drill handle, and the ENDOTINE installation instrument and a sterilization tray.

Substantial Equivalence:

Establishment of equivalence is based on similarities of intended use, fundamental scientific technology, labeling, design, dimensional specification, performance specification, ergonomics of the patient-user interface, packaging and expiration dates, and sterilization. Based on the criteria set forth in 21 CFR 807.87 and under the New 510(k) Paradigm, it is the belief of Coapt Systems that the ENDOTINE device cleared to market in K014153 and the proposed ENDOTINE device are substantially equivalent in all aspects expect material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2002

Coapt Systems, Inc.
c/o Ms. Shelley Trimm
RCQ Consulting
1152 Navarro Street
Santa Rosa, California 95401

Re: K023922
Trade/Device Name: Coapt Systems ENDOTINE Device™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 22, 2002
Received: November 25, 2002

Dear Ms. Trimm:

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). 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,

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

STATEMENT FOR INDICATIONS FOR USE

510(k) Number: ~~K014153~~ K023922

Device Name: Coapt Systems ENDOTINE Device

Indication for Use:

The ENDOTINE Device is intended for use in browplasty surgery. The ENDOTINE device is specifically intended for use to fixate the sub-dermis to the cranial bone in browplasty procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (YES) NO or Over-the-Counter Use Yes (No)

(Division Sign-Off)

510(k) Number:

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K023922