# 11 510(k) SUMMARY

## 11.0 510(k) Summary

Coapt Systems is providing a summary of the safety and effectiveness information available for the ENDOTINE Midface™ B 4.5 Device. This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92 and pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990.

**SPONSOR/APPLICANT NAME AND ADDRESS**

Coapt Systems, Inc.
1820 Embarcadero Road
Palo Alto, CA
Telephone: (650) 461-7600
Facsimile: (650) 213-9336

**CONTACT INFORMATION**

Lori DonDiego
Director, Regulatory Affairs
Coapt Systems, Inc.
1820 Embarcadero Road
Palo Alto, CA
Telephone: (650) 461-7647
Facsimile: (650) 213-9336
Email: ldondiego@coaptsystems.com

**DATE OF PREPARATION OF 510(K) SUMMARY**

**July 6, 2004**

**DEVICE TRADE OR PROPRIETARY NAME**

ENDOTINE Midface™ B 4.5 Device

**DEVICE COMMON OR CLASSIFICATION NAME**

Classification Name: Smooth or threaded metallic bone fixation fastener
Regulation Number: 888.3040
Class: II
Product Code: HWC

## IDENTIFICATION OF THE LEGALLY MARKETED DEVICES TO WHICH EQUIVALENCE IS BEING CLAIMED

| Name of Predicate Device | Name of Manufacturer | 510(k) or PMA Number |
|---|---|---|
| ENDOTINE Midface™-ST 4.5 Device | Coapt Systems, Inc | K032698 |
| LactoSorb® Panels | Walter Lorenz Surgical | K974309 |

## DEVICE DESCRIPTION

The ENDOTINE Midface™-ST 4.5 consists of two components: (1) a fixation platform with anchoring leash, and (2) a screw anchor. This device is supplied sterile for single use only.

The ENDOTINE Midface™ B Instrument Kit is packaged separately from the implant device and is provided to the user non-sterile. The kit is comprised of the following tools that aid in the deployment and anchoring of the implant device:

- Sterilization tray (lid, base and mat) to house the instruments for transport and sterilization
- Drill bit for creating a hole in the infra-orbital rim
- Tapping tool to create the threads in the drilled hole to conform to the anchor screw
- Insertion tool to grasp and deploy the anchor screw
- Clipper tool to remove the screw flange and excess leash length

## INTENDED USE STATEMENT

The ENDOTINE Midface™ B 4.5 is intended for use in subperiosteal midface suspension surgery. Specifically, the ENDOTINE Midface™ B 4.5 is indicated for use in suspending the subcutaneous tissues of the midface from the infra-orbital rim or zygoma via an anchoring leash.

## SUBSTANTIAL EQUIVLANCE COMPARISON

1. Indications Summary

The "Indication Statement" for the ENDOTINE Midface™ B 4.5 and its predicate, the ENDOTINE Midface™–ST 4.5, are nearly identical. Both devices are effective in securely lifting midfacial tissues, and this is substantiated by bench and performance testing presented.

2. Technological Characteristics Summary

The ENDOTINE Midface™ B 4.5 is substantially equivalent in design, materials and fundamental scientific technology to the ENDOTINE Midface™-ST 4.5 and LactoSorb Panel predicate devices.

3. Performance Summary

A study of the comparative performance of the ENDOTINE Midface™ B 4.5 and its predicates raised no different questions of safety or effectiveness for the proposed device, and the results suggest the ENDOTINE Midface™ B 4.5 performs as well as the selected predicate for its intended use.

**SUBSTANTIAL EQUIVALENCE CONCLUSION**

The ENDOTINE Midface™ B 4.5 is an innovative and effective application of the FDA-approved ENDOTINE™ Multi-Point Technology. Based on the design, materials, function, intended use, and performance evaluations, the ENDOTINE Midface™ B 4.5 is substantially equivalent to the two selected predicate devices. All of the predicate devices listed in this application are currently marketed under the Federal Food, Drug and Cosmetic Act.

The ENDOTINE Midface™ B 4.5 raises no new or different safety or effectiveness issues when compared to the predicate devices. The safety and effectiveness of the ENDOTINE Midface™ B 4.5 is supported by appropriate tests and evaluations, including bench testing of performance characteristics and comparison studies with the Midface ST predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2004

Ms. Lori DonDiego
Director, Regulatory Affairs
Coapt Systems, Inc.
1820 Embarcadero Road
Palo Alto, California 94303

Re: K041835
Trade/Device Name: Endotine Midface™ B 4.5 Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Bone fixation screw
Regulatory Class: II
Product Code: HWC, GAN
Dated: July 6, 2004
Received: July 7, 2004

Dear Ms. DonDiego:

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. 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 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 Miriam C. Provost

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 STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): Not yet assigned

Device Name: ENDOTINE Midface™ B 4.5 Device

Indications For Use: The ENDOTINE Midface™ B 4.5 is intended for use in subperiosteal midface suspension surgery. Specifically, the ENDOTINE Midface™ B 4.5 is indicated for use in suspending the subcutaneous tissues of the midface from the infra-orbital rim or zygoma via an anchoring leash.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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**



**510(k) Number** K041835

[redacted]