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## 11 510(k) SUMMARY

### 11.0 510(k) Summary

JUN 12 2006

Coapt Systems is providing a summary of the safety and effectiveness information available for the ULTRATINE Forehead™ 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

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Telephone: (650) 461-7600  
Facsimile: (650) 213-9336

#### CONTACT INFORMATION

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Director, Regulatory and Clinical Affairs  
Coapt Systems, Inc.  
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#### DATE OF PREPARATION OF 510(K) SUMMARY

January 31, 2006

#### DEVICE TRADE OR PROPRIETARY NAME

ULTRATINE Forehead™ Device

#### DEVICE COMMON OR CLASSIFICATION NAME

Classification Name: Smooth or threaded metallic bone fixation fastener  
Regulation Number: 878.3040  
Class: II  
Product Code: HWC

**IDENTIFICATION OF THE LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCE IS BEING CLAIMED**

<b>Name of Predicate Device</b>	<b>Product Code</b>	<b>Name of Manufacturer</b>	<b>510(k) or PMA Number</b>
ENDOTINE Forehead™	HWC	Coapt Systems, Inc	K023922
Vicryl	GAM	Ethicon	K944110

**DEVICE DESCRIPTION**

The ULTRATINE Forehead™ consists of a bioabsorbable implant. This device is supplied sterile for single use only.

**INTENDED USE STATEMENT**

The ULTRATINE Forehead™ is intended for use in subperiosteal browplasty surgery. The ULTRATINE Forehead is specifically indicated for use to fixate the subdermis to the cranial bone in browplasty.

**SUBSTANTIAL EQUIVALENCE COMPARISON****1. Indications Summary**

The "Indication Statement" for the ULTRATINE Forehead™ is substantiated by the results of the performance evaluations and comparison testing to the predicate devices. The selected predicate devices are used in forehead lift procedures. The differences between the ULTRATINE Forehead™ and the predicate devices does not affect the safety and effectiveness of the ULTRATINE Forehead™.

**2. Technological Characteristics Summary**

The ULTRATINE Forehead™ is substantially equivalent in design, materials and fundamental scientific technology to the predicate devices. Further, the technological characteristics of the ULTRATINE Forehead™ are similar to many absorbable, implantable general, orthopedic and plastic surgery devices legally distributed by other manufacturers. Any differences between the ULTRATINE Forehead™ and the predicate devices are minor and do not raise issues regarding safety or effectiveness.

**3. Performance Summary**

The ULTRATINE Forehead™ performance data meet the applicable standards and fulfill the device requirements as defined in the user specifications.

**SUBSTANTIAL EQUIVALENCE CONCLUSION**

Based on the design, materials, function, intended use, and performance evaluations discussed herein, Coapt Systems believes the ULTRATINE Forehead™ is substantially equivalent to the predicate devices currently marketed under the Federal Food, Drug and Cosmetic Act. No new issues of safety or effectiveness were raised for the ULTRATINE Forehead™ Device. Therefore, safety and effectiveness are reasonably assured, justifying 510(k) clearance for commercial sale.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 12 2006

Coapt Systems, Inc.  
% Ms. Linda Ruedy  
Director, Regulatory and Clinical Affairs  
1820 Embarcadero Road  
Palo Alto, California 94303

Re: K060249

Trade/Device Name: ULTRATINE Forehead™  
Regulation Code: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulation Class: II  
Product Code: HWC  
Dated: April 28, 2006  
Received: April 28, 2006

Dear Ms. Ruedy:

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.

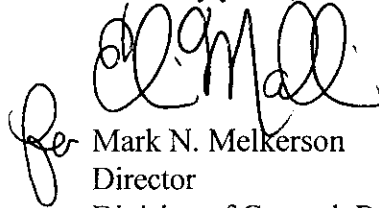
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 (240) 276-0115. 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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large initial "M". To the left of the signature, there is a small, stylized handwritten mark that looks like "for".

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

