SYNTHES®

OCT 22 1999

3.0 Summary of Safety and Effectiveness Information

K990687

SPONSOR:	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Angela Silvestri
DEVICE NAME:	Synthes (USA) Locking Reconstruction Plate with Condylar Head
CLASSIFICATION:	21 CFR 872.4760 Bone Plate
PREDICATE DEVICE:	Synthes (USA) Locking Reconstruction Plate System
DEVICE DESCRIPTION:	The Locking Reconstruction Plate with Condylar Head is a one piece reconstruction plate with a solid condylar head. The plate features compression screw holes that are internally threaded to accept the 2.4 - 3.0 mm locking screws or standard 2.4 mm self-tapping cortex screws and has notched sides and undersides to facilitate contouring. The plates are available in three sizes for right and left placement.
INTENDED USE:	Synthes (USA) Locking Reconstruction Plate with Condylar Head is intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).
MATERIAL:	Titanium

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 2009

Ms. Angela J. Silvestri
Manager, Regulatory Affairs
SYNTES (USA)
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K990637
Trade/Device Name: Synthes (USA) Locking Reconstruction Plate (LRP) with Condylar Head
Regulation Number: 21 CFR 872.3960(c)(2)
Regulation Name: Mandibular Condyle Prosthesis
Regulatory Class: III
Product Code: NEI
Dated: July 23, 1999
Received: July 26, 1999

Dear Ms. Silvestri:

This letter corrects our substantially equivalent letter of October 22, 1999.

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.

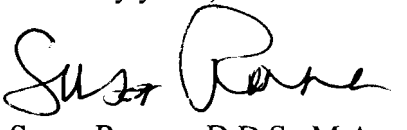
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2.0 Indications for Use Statement

510(k) Number (if known): K990637

Device Name: Synthes (USA) Locking Reconstruction Plate with Condylar Head

Indications/Contraindications:

Synthes (USA) Locking Reconstruction Plate with Condylar Head is intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).

(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)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K990637