JUL 27 2001

K990667

510(K) SUMMARY
(as required by 807.92 9c))

Submitter of 510(K):

KLS-Martin, L.P.
11239-1 St. Johns Industrial Pkwy. S.
Jacksonville, Florida 32246

Phone: 904-641-7746
Fax: 904-641-7378

Contact Person: Jennifer Damato

Date of Summary: July 27, 2001

Trade Name: KLS-Martin Temporary Condylar Implant

Classification Name: Temporary Condylar Implant

Predicate Device: Leibinger Temporary Condylar Implant

Device Description/ Comparison:

The KLS-Martin Temporary Condylar Implant is a solid condylar head which attaches with fastening screws to a KLS-Martin Fracture/Reconstruction Plate. The KLS-Martin Temporary Condylar Implant is available for left and right placement.

Intended Use:

The KLS-Martin Temporary Condylar Implant is only intended for temporary reconstruction of the mandibular condyle in patients who have undergone resective procedures to remove malignant or benign tumors 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).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2001

KLS-Martin L.P.
C/O Mr. Arhtur J. Ward
Medical Device Consultant
Regulatory & Marketing Services, Incorporated
3234 Ella Lane
New Port Richey, Florida 34655

Re: K990667
Trade/Device Name: KLS-Martin Temporary Condylar Implant
Regulation Number: 872.3960
Regulatory Class: III
Product Code: NEI
Dated: April 27, 2001
Received: April 30, 2001

Dear Mr. Ward:

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 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). 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 requirements, 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) 594-4692. 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 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/dsma/dsmamain.html".

Sincerely yours,

Patricia Cucenda /for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990667

Device Name: KLS-Martin Temporary Condylar Implant

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K990667

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801-109)