

DEC 21 1999

K980760

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

Submitter of 510(k): Regulatory & Marketing Services, Inc. (RMS)
3234 Ella Lane
New Port Richey, FL 34655
Phone: ⁷²⁷ ~~813~~-376-4154
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Contact Person: Ed Ransom

Date of Summary: February 25, 1998

Trade Name: KLS-Martin MMF Screw

Classification Name: Screw, Fixation

Predicate Device: Leibinger IMF Screw: K963030

**Device Description/
Comparison:** The KLS-Martin MMF Screws provide temporary occlusal and fracture stabilization which can be achieved within a matter of minutes. These screws may be applied prior to or after exposure of the fracture.

Intended Use: The KLS-Martin MMF Screw is intended for use in maxillomandibular fixation to provide stabilization of fractures of the maxilla, mandible, or both.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Arthur J. Ward
Medical Device Consultant
Regulatory & Marketing Services, Incorporated
3234 Ella Lane
New Port Richey, Florida 34655

Re: K980760
Trade Name: KLS-Martin MMF Screw
Regulatory Class: II
Product Code: DZL
Dated: November 7, 1999
Received: November 9, 1999

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 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 (Pre-market 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

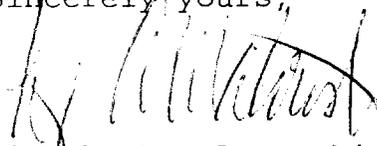
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obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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" (21 CFR 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/dsmamain.html>".

Sincerely yours,



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

Enclosure

