

MAR 18 1998

K974785

510(k) Summary

Device Proprietary Name: OsteoMed Auto-Drive Bone Screw

Device Common Name: Small Bone Screw

Classification Name: Smooth or threaded metallic bone fixation fastener 21 CFR 888.3040

Name of Submitter: OsteoMed Corporation

Contact Person: Bruce Horowitz
Manager, Regulatory Affairs/Quality
OsteoMed Corp.
3750 Realty Road
Dallas, TX 75244
Telephone: (972) 241-3401
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Date Prepared: 12/19/97

Summary:

This submission describes the Auto-Drive™ bone screws intended for use in internal fixation of small bones including the cranifacial and maxillofacial skeleton and hand, secondary to trauma or for reconstruction. The Auto-Drive™ bone screws are available in 1.6 mm and 2.0 mm diameters with lengths ranging from 4 mm to 8 mm.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the KLS Martin Centre-Drive Drill-free™ Screw (K944565) and the Leibinger® Self-Drilling Screw (K970912). All of the screw systems are intended for use in internal fixation of small bones including the cranifacial and maxillofacial skeleton and hand, secondary to trauma or for reconstruction. All of the screws are self drilling and manufactured from Titanium alloy. The basic operational principle is the same for all three screws, e.g., they are self drilling and can be inserted in one step. Indications are also equivalent for each of the devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 18 1998

Mr. Bruce R. Horowitz
Manager, Regulatory Affairs/Quality Assurance
OsteoMed Corporation
3750 Realty Road
Dallas, Texas 75244

Re: K974785
Trade Name: Auto-Drive Bone Screw
Regulatory Class: II
Product Code: HWC
Dated: December 19, 1997
Received: December 22, 1997

Dear Mr. Horowitz:

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 (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 requirement, 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.

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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) 594-4659. 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,


for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OSTEOMED "Indications for Use" Submission

510(k) Number:

| | |
|---------------------|--|
| Device Name: | Osteomed Auto-Drive Bone Screw Smooth or threaded metallic bone fixation fastener |
| Indication for Use: | Fixation secondary to trauma or reconstruction of the craniofacial and maxillofacial skeleton and bones of the hand |

Prescription Use X
(Per 21 CFR 801.109)

Samuel P. Pagan

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974785