JAN 20 1999

K982006

MICOMED - HALM ZIELKE INSTRUMENTATION;
510(k) Summary

Company: Schafer MICOMED GmbH
Box 1664
73606 Schomdorf, Germany
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Tradename: MICOMED - Halm Zielke Instrumentation

Classification: Spinal Intervertebral Body Fixation Orthosis

Description: The principal components of the MICOMED - Halm Zielke Instrumentation, which is a low profile spinal fixation system, are as follows: Halm plates, screws, threaded rods, standard hex nut for threaded rods, fluted rods, vertebral clamps (double hole). Additional instrumentation includes: an awl, insertion instruments (Halm plates, threaded rod screws), screw wrench for hex nut, rod pusher for fluted rod, rod benders, in situ rod bender, grip tongs (threaded rod, fluted rod), and hook grasp tong.

The principal components of the MICOMED - Halm Zielke Instrumentation are utilized in the following manner. First, the most cranial and caudal Halm plates are each attached to the lateral aspect of the vertebral body with two screws (countersunk, Zielke), and then additional plates are attached as needed. The threaded rod is then connected to the top of the Zielke screws, and anchored with the standard hex nuts. Once the threaded rod is properly connected to the Halm plates, partial correction of the scoliotic deformity is performed before attaching the pre-bent fluted rod by closing the lid of the Halm plate and securing with the head screws. The secured fluted rod can then be rotated around its longitudinal axis to achieve an appropriate level of derotation and re-lordosation. If this system is used in the thoracic spine, rod rotation is performed in reverse to produce or enhance physiological kyphosis. Additionally, segmental compression or distraction can be used to increase or decrease lordosis or kyphosis as desired.

Material: The components of the MICOMED - Halm Zielke Instrumentation are manufactured from implant grade stainless steel (316LS) conforming to ASTM F1314 specifications or implant grade titanium conforming to ASTM F136.

Indications: The Halm Zielke Instrumentation System is an anterior spinal fixation system indicated for spinal deformities such as scoliosis, kyphosis, and lordosis and thoracolumbar spinal instability caused by fracture.

Performance: The inherent stability (stiffness) of the MICOMED - Halm Zielke

Data: Instrumentation has been compared to Zielke-VDS in two different models. In addition, fatigue testing was performed. The results demonstrate that the calf and artificial spines were much more resistant to various deformational forces (axial compression, flexion, extension, lateral bending, torsion) after the MICOMED - Halm Zielke Instrumentation was applied as opposed to Zielke-VDS. Moreover, when the calf spines were subjected to one million cycles of axial compression at loads of 1400 Newtons (N) and 2600 N, none exhibited any evidence of device failure.

Substantial Equivalence: The MICOMED - Halm Zielke Instrumentation is equivalent to the Zielke-Ventral Derotation Spondylodesis, Kaneda SR™ Anterior Spinal System, and Anterior Isola Spinal System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 1999

Micomed
c/o Ms. Charmaine Henderson
511 Catalina Road
Fullerton, California 92835

Re: K982006
Trade Name: Halm Zielke Instrumentation
Regulatory Class: II
Product Code: KWQ
Dated: October 23, 1998
Received: October 30, 1998

Dear Ms. Henderson:

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.

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,

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

INDICATIONS FOR USE ENCLOSURE

510k: K982006

Device: Halm Zielke Instrumentation System

Indications for Use:

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(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982006

X Prescription use

__Over the Counter Use