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510(k) Summary
for the Verticor K-Wire System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the Verticor K-Wire System FEB 28 2011

Date Prepared: 12/31/2010

1. **Submitter:**
Verticor, LTD
600 N. Marienfeld Street, Suite 350
Midland, TX 79701

Contact Person:
J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. **Trade name:** Verticor K-Wire System
Common Name: K-wires
Classification Name: Pin, Fixation Smooth/ Pin, Fixation, Threaded
21 CFR 888.3040
HTY/JDW
Class II

3. **Predicate or legally marketed devices which are substantially equivalent:**
KMedic External Fixation Devices (K030336 - Teleflex Medical Group)
SMT Schilling Kirschner/Guide Wires (K100736 - SMT Schilling Metailtechnik GmbH)

4. **Description of the device:**
K-wires are sharpened or blunt, smooth stainless steel pins. They come in different sizes and are used to hold bone fragments together (pin fixation) or to provide an anchor for skeletal traction. To ensure the multi-use of these devices, many different models are available. Threaded K-wires are available for situations where backing out of the pin is undesirable.

Materials:
316L stainless steel per ASTM F138

Function:
The K-wires are used to hold bone fragments together (pin fixation) or to provide an anchor for skeletal traction.

5. **Substantial equivalence claimed to predicate devices**
Verticor K-Wires are substantially equivalent to the KMedic External Fixation Devices and SMT Schilling Kirschner/Guide Wires in terms of intended use, design, and materials used. The table below compares the features and characteristics of the Verticor K-Wires to these predicate devices.

Device Name / Items	Verticor K-Wire System	KMedic External Fixation Devices	SMT Schilling Kirschner/Guide Wires
Sponsor	Verticor, LTD	Teleflex Medical Group	SMT Schilling Metailtechnik GmbH
510(k) Number	--	K030336	K100736
Device Classification Name	Pin, Fixation Smooth/ Pin,	Pin, Fixation Smooth/ Pin,	Pin, Fixation Smooth/ Pin,

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Device Name / Items	Verticor K-Wire System	KMedic External Fixation Devices	SMT Schilling Kirschner/Guide Wires
	Fixation, Threaded	Fixation, Threaded	Fixation, Threaded
Product Code	HTY/JDW	HTY/JDW	HTY/JDW
Regulation #	21 CFR 888.3040	21 CFR 888.3040	21 CFR 888.3040
Classification	Class II	Class II	Class II
Indications for Use	See below	See 510(k) Summary	See 510(k) Summary
Material	316L stainless steel	316L stainless steel	316L stainless steel
Length	150 up to 450mm	102 up to 305mm	60 up to 500mm
Diameter	0.7 up to 1.6mm	0.7 up to 1.6mm	0.6 up to 6.35mm
Surface	Complete or partial smooth and/or threaded	Complete smooth or fully threaded	Complete or partial smooth and/or threaded, with or without threading cutter
Tip geometry	•diamond or trocar point •round •flat with or without spherical shape	•Double or single end trocar point •Double or single end diamond point	•diamond or trocar point •round •flat •with or without 3- or 4- shank ends •with or without spherical shape
Sterility	Non-sterile, sterilized in hospital	Non-sterile, sterilized in hospital	Non-sterile, sterilized in hospital

6. **Intended Use:**

The Verticor K-Wire System is intended for use in fixation of bone fractures, fusion of joints or bone reconstruction, for osteotomies in the presence of adequate immobilization and as guide pins for insertion of other implants.

7. **Clinical Test Summary**

No clinical studies were performed.

8. **Conclusions Nonclinical and Clinical**

Verticor K-Wire System is substantially equivalent to the predicate devices in terms of indications for use, design, material, and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Verticor, LTD
% Mr. J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, Texas 78681

FEB 28 2011

Re: K110047
Trade/Device Name: Verticor K-Wire System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY, JDW
Dated: December 31, 2010
Received: January 6, 2011

Dear Mr. Webb,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110047

Device Name: Verticor K-Wire System

Indications for Use:

The Verticor K-Wire System is intended for use in fixation of bone fractures, fusion of joints or bone reconstruction, for osteotomies in the presence of adequate immobilization and as guide pins for insertion of other implants.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110047