AUG 2 8 2001

510(K) SUMMARY

Ortelius 800

510(k) Number K011827 p1/2

Applicant's Name:

Orthoscan Ltd.
P.O.B. 281 Yokneam Eilit, 20692 Israel
Tel: 972-4-9937363
Fax: 972-4-9937364

Contact Person:

Shoshana Friedman, RAC
Push-med Ltd.
117 Ahuzah St.
Ra'anana 43373, Israel
Tel: 972-9- 7718130
Fax: 972-9-7718131

Date Prepared:

June 2001

Trade Name:

Ortelius 800

Classification Name:

Goniometer

Classification:

The FDA has classified Goniometer as class II devices (product code 87 KQX, Regulation No. 888.1500) and they are reviewed by the Orthopedic Panel.

K011827 p2/2

Predicate Device:

- Orthopedic Systems, Inc. Scoliometer cleared under K832494
- Skill Technologies, 3D-SPINE, cleared under K962377

Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, the Ortelius 800 complies with voluntary standards IEC 60601-1; EN 60601-1; UL 2601-1; CSA-C22.2; IEC 60601-2 1993; EN 60601-4; EN-1441.

Intended Use:

The Ortelius 800 is a prescriptive device intended to measure the angle of spinal deformity as an aiding tool for the diagnosis and monitoring of spinal deformities such as scoliosis and kyphosis.

The Ortelius 800 may be used in medical clinics/institutes.

Device Description:

The Ortelius 800 is a device designed for the measuring and monitoring spine deformities.

The Ortelius 800 enables the following features:
- Spine curve reconstruction based on the points sampled by the Sensor.
- Automatically calculated spine deformity angles of the primary curve.
- Indication of the extreme vertebra from which the spine deformity angle was calculated.

Substantial Equivalence:

Orthoscan Ltd. believes that, based on validations and performance testing results, the Ortelius 800 is substantially equivalent to its predicate device cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2001

Ms. Shoshana Friedman, RAC
Push-med Ltd.
117 Ahuza Street
Ra'ananna 43373
Israel

Re: K011827
Trade/Device Name: Ortelius 800
Regulation Number: 888.1500
Regulatory Class: II
Product Code: KQX
Dated: June 6, 2001
Received: June 12, 2001

Dear Ms. Friedman:

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) 594-4659. 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" (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,

for Mark N Melkerson

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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K011827

Device Name: Ortelius 800

Indications for Use:

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The Ortelius 800 may be used in medical clinics/institutes.

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

510(k) Number _____

Prescription Use _____ OR Over the Counter Use_____
(Per 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011827