K033413

JAN - 7 2004

SECTION 7 - SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant:

Mazor Surgical Technologies Ltd.
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Corresponding Official:

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Device Name: SpineAssist Device

Device trade or proprietary name: SpineAssist Device

Common Name: Surgical Navigation System / Image Guided Surgery

Classification Name: Stereotaxic Instrument, 21 CFR Section 882.4560

Description of the Device:

The SpineAssist device is a computer controlled miniature medical image-guided surgery (IGS) system which serves as a technological platform for solutions that provide unprecedented levels of accuracy, precision and accessibility in performing orthopedic procedures. The SpineAssist is designed to assist surgeons in precisely guiding handheld surgical tools in line with a computerized, image-based pre-operative plan along given trajectories. The system's software processes fluoroscopic and CT images via proprietary algorithms and automatically exports the desired coordinates to the MSG, which positions its articulating arm and tool guide. Through the bone-attaching procedure, the SpineAssist device attaches to the bone on which

the procedure is being performed and assists surgeons in precisely guiding handheld surgical tools in line with the computerized, image-based, pre-operative plan.

The main components of the SpineAssist device include:

A. Planning System;
B. Workstation; and
C. Miniature Surgical Guidance System - MSG

Intended Use:

The SpineAssist is indicated for precise positioning of surgical instruments during spinal stabilization surgery. The device enables pre-operative planning of the surgical procedure and subsequent spatial positioning and orientation of the surgical tool during intra-operative procedures.

Performance Data:

Testing was carried out to assure compliance with recognized electrical safety standards. Mazor Surgical Technologies has certified compliance with the EN 60601-1 standard for electrical safety and compliance with the EN 60601-1-2 standard for electromagnetic compatibility. Tests were also carried out to satisfy the requirements of the IEC 60601-1-4 standard and the FDA Guidance for the Content of PreMarket Submissions for Software Contained in Medical Devices. Additional device performance tests were performed to validate the accuracy and repeatability of the device.

Predicate Device:

The SpineAssist device is substantially equivalent to a combination of the following devices. Device names, manufacturers and 510(k) numbers are designated in the following table.

Device	Manufacturer	Type of Device	510(k) Number
Neuromate	Brainlab AG	Stereotaxic Instrument	K963256, K991081
Vector Vision	Integrated Surgical Systems Inc.	Stereotaxic Instrument	K010968, K021306
Navitrack	OrthoSoft Inc.	Stereotaxic Instrument	K981315, K031156

K033413

Technological Characteristics Compared to Predicate Device

The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, etc., and the intended use of the SpineAssist device are substantially equivalent to the predicate devices cited above. The differences that exist between the devices, relative to the technical specifications do not raise new issues of safety or effectiveness regarding the SpineAssist device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2004

Mazor Surgical Technologies Ltd.
c/o Ms. Ahava Stein
Regulatory Affairs Consulting
Beit Hapa'amon (Box 124)
20 Hata'as St. (Room 213)
44425 Kfar Saba
Israel

Re: K033413
Trade/Device Name: SpineAssist Device
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: II
Product Code: HAW
Dated: October 22, 2003
Received: November 4, 2003

Dear Ms. Stein:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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

Enclosure

Indications for Use

510(k) Number (if known): K033413

Device Name: SpineAssist Device

Indications For Use: The SpineAssist is indicated for precise positioning of surgical instruments during spinal fusion stabilization surgery. The device enables pre-operative planning of the surgical procedure and subsequent spatial positioning and orientation of the surgical tool during intra-operative procedures.

Prescription Use ✓ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K033413