SECTION 5 - 510(K) SUMMARY OF SAFETY & EFFECTIVENESS

SPINEASSIST™ SYSTEM

510(k) Number K063607

AUG 23 2007

Applicant's Name:

Company name:	Mazor Surgical Technologies Ltd.
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Contact Person:

Official Correspondent:	Ahava Stein
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Name of the device:

SpineAssist™ System

Trade or proprietary name, if applicable:

SpineAssist™ System

Common or usual name:

Surgical Navigation System / Image Guided Surgery

Establishment Registration No.:

3005075696

Classification Name:

Stereotactic Instrument

Classification:

FDA has classified Stereotactic devices as a Class II medical device, with product code HAW and 21 CFR classification code 882.4560. Review by the General & Plastic Surgery Devices Panel.

Predicate Device:

The SpineAssist™ system is substantially equivalent to the original SpineAssist™ system (manufactured by Mazor Surgical Technologies Ltd., and the subject of 510(k) document no. K033413 and K051676) and the StealthStation System (manufactured by Medtronic and the subject of 510(k) document nos. K954276 to K050438). A comparison table and detailed discussion are presented in Section 12 of this application.

Device Description:

The SpineAssist™ system 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 or implants 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 SpineAssist device, which positions its articulating arm and tool guide. Using a special bone attachment component (i.e., a clamp and bridge or the Hover-T bridge) the SpineAssist device attaches to the bone in the area where the procedure is being performed and assists surgeons in precisely guiding handheld surgical tools or implants according to the computerized, image-based, pre-operative plan.

The main components of the SpineAssist™ system include:

A. SpineAssist™ device
B. Workstation
A. Accessories including clamp, bridge, Hover-T bridge, targets, prism, wedge, etc.

Intended Use / Indication for Use:

The SpineAssist™ System is indicated for precise positioning of surgical instruments or implants during thoracic and lumbar spinal surgery. The SpineAssist™ system may be used in either open or percutaneous procedures.

Comparison of Technological Characteristics with the predicate device:

The modified SpineAssist system is identical to the original SpineAssist system regarding all components, design, materials, basic scientific technology, etc. The only differences are that the "modified" device is intended for general spinal surgery and a software change enabling a quicker and easier registration process using two fluoroscopy images instead of four and one target instead of two. The SpineAssist also includes some new accessories, including the wedge and prism for accessing extreme angles or trajectories, additional sterile sheaths to

cover the C-arm and X-ray shield and a few other minor accessories that are described later in this submission.

Non-Clinical Performance Data

The following performance tests were conducted on the SpineAssist™ system:

1. Software Validation (IEC 60601-1-4 & FDA Guidelines)
2. Biocompatibility Testing (ISO 10993)
3. Osteoid Osteoma Case Study
4. Thoracic Hover-T Case Study
5. General Spinal Accuracy Test
6. New Imaging and Lateral to 30 degree Accuracy Test
7. Use of Prisms in Translaminar Facet Cases Study
8. Hover-T Accuracy Test Results Report
9. Hover-T Stability Test Results Report
9. Vertebroplasty Summary Report

Clinical Performance Data

Not Applicable

Conclusions Drawn from Non-Clinical and Clinical Tests:

The performance tests demonstrate that SpineAssist system may be safely and effectively used in general spinal surgical procedures requiring precise positioning of surgical instruments or implants during open or percutaneous thoracic and lumbar spinal surgery. The software validation and accuracy performance tests demonstrate that the SpineAssist system meets its design and performance specifications and is substantially equivalent to the previously cleared SpineAssist system.

Substantial Equivalence:

In summary, the intended use of the modified SpineAssist™ system is substantially equivalent to a combination of the original SpineAssist™ system and the StealthStation device. Furthermore, the basic technological characteristics of the modified SpineAssist™ system are identical to the original SpineAssist™ system, except for the minor software changes enabling an easier registration process using only one target. The differences in the technological characteristics do not raise new questions of safety and effectiveness. Consequently, the SpineAssist™ system is substantially equivalent to the original SpineAssist™ system and the StealthStation device.

Performance Standards:

The SpineAssist™ system complies with the voluntary recognized standards:

1. Software Validation (IEC 60601-1-4 & FDA Guidelines)
2. Biocompatibility Testing (ISO 10993)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mazor Surgical Technologies Ltd.
% A. Stein Regulatory Affairs Consulting
Ahava Stein
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Kfar Saba
Israel 44425

AUG 23 2007

Re: K063607
Trade/Device Name: SpineAssist™ System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: August 2, 2007
Received: August 8, 2007

Dear Ahava 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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

SECTION 4 - INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K063607

Device Name: SpineAssist™ System

Indications for use: The SpineAssist™ system is indicated for precise positioning of surgical instruments or implants during thoracic and lumbar spinal surgery. The SpineAssist™ system may be used in either open or percutaneous procedures.

Prescription Use ___√___ OR Over-The-Counter Use___
(Per 21 C.F.R. 801 Subpart D) (Optional Format Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K063607

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