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

SPINEASSIST™ SYSTEM

MAY 2 3 2008

510(k) Number K 073467

Applicant's Name:

Company name:	Mazor Surgical Technologies Ltd.
Address:	7 HaEshel Str. P.O.B. 3104 Southern Caesarea Industrial Park 38900 ISRAEL
Tel.:	+972-4-6270171
Fax:	+972-4-6377234
e-mail:	armin@mazorst.com

Contact Person:

Official Correspondent:	Ahava Stein
Company name:	A. Stein – Regulatory Affairs Consulting
Address:	Beit Hapaamon (Suite 213) 20 Hata'as Str. (Box 124) Kfar Saba 44425 ISRAEL
Tel:	+ 972-9-7670002
Fax:	+972-9-7668534
e-mail:	asteinra@netvision.net.il

Name of the device:

SpineAssist™ System

Trade or proprietary name, if applicable:

SpineAssist™ System

Common or usual name:

Surgical Navigation System / Image Guided Surgery

1/4

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 Division of General, Restorative and Neurological Devices.

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, K051676 and K063607) 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 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, the Hover-T / Bi-lateral Hover-T bridge, the Bed Mount Hover-T or the Cervical Kit) 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 according to the computerized, image-based, pre-operative plan.

The main components of the SpineAssist™ system include:

A. SpineAssist™ device
B. Workstation
C. Accessories including the Clamp Kit for less invasive procedures, the MIS platforms: Hover-T, Bi-lateral Hover-T, Bed Mount Hover-T and the Cervical Kit, the last one intended for less invasive procedures.

The SpineAssist was previously cleared under K033413, K051676 and K063607. This 510(k) submission describes the addition of two accessories (Bilateral hover-T bridge and Bed Mount stabilization frame) that enable increased accessibility for the device over the entire range of the vertebral column, including cervical approaches; and the software changes that were introduced as improvements in user interface, as needed from the addition of the new approaches and in response to user's feedback.

Intended Use / Indication for Use:

The SpineAssist™ System is indicated for precise positioning of surgical instruments or implants during general 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 also for cervical spinal surgery; more versatility is provided in minimally invasive spinal surgery, by allowing stabilization using a Bed Mount stabilizing frame (thus reducing the need to stabilize the device via more invasive pelvic screws) and the Bi-lateral Hover-T; and software changes providing more user interface features improving procedure workflow. To enable cervical approach, the SpineAssist includes some new accessories, including the Bilateral hover-T bridge and the Bed Mount stabilizing frame. The combination of these accessories allows extended trajectories and range of operation for the device, in three new mounting options: Bilateral Hover-T, Bed-Mount Hover-T, and Cervical Kit.

Non-Clinical Performance Data
The following performance tests were conducted on the SpineAssist™ system, in order to validate stability and accuracy of the device under the extended intended use, i.e. cervical and minimally invasive procedures using the new stabilizing platforms:

1. Software Validation (IEC 60601-1-4 & FDA Guidelines)
2. Bed Mount Hover-T Stability Test
3. Relative Movement of C2 Test
4. Cervical Bridge Rigidity Test
5. Bi-lateral Hover-T Rigidity Test
6. Cervical Accuracy C1-C6 Test
7. Bed Mount Hover-T Accuracy T6-T12

Stability and accuracy tests were performed on cadavers to simulate real clinical procedures.

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 spinal surgical procedures requiring precise positioning of surgical instruments or implants during open or percutaneous 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. 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)

5/5

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
20 Hata'as St
44425 Kfar Saba
Isreal

MAY 23 2008

Re: K073467
Trade/Device Name: SpineAssist System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: May 15, 2008
Received: May 22, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

INDICATIONS FOR USE

510(k) Number (if known): K073467

Device Name: SpineAssist System

Intended Use Statement:

The SpineAssist™ System is indicated for precise positioning of surgical instruments or implants (pedicle screws, plates and etc.) during general 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 K073467