SEP - 8 2005

Appendix B:

SECTION 6 - SUMMARY OF SAFETY AND EFFECTIVENESS

K051676
(Premarket Notification [510(k)] Number)

1. Applicant

Mazor Surgical Technologies Ltd.
7 HaEshel Str.
P.O.B. 3104
Southern Caesarea Industrial Park 38900
ISRAEL
Tel: +972-4-6270171
Fax: +972-4-6377234

Corresponding Official:

Name: Ahava M. Stein, Consultant
Address: A. Stein - Regulatory Affairs Consulting
Beit Hapa'amon (Box 124)
20 Hata'as St.
44425 Kfar Saba
ISRAEL
Tel: +972-9-767 0002
Fax: +972-9-766 8534

2. Device Name

Device Name: SpineAssist System

Device trade or proprietary name: SpineAssist System

Common Name: Surgical Navigation System / Image Guided Surgery

Classification Name: Stereotaxic Instrument, 21 CFR Section 882.4560

3. Predicate Devices

The modified SpineAssist device is substantially equivalent to the following device:

Device	Manufacturer	510(k) No.
SpineAssist	Mazor Surgical Technologies Ltd.	K033413

4. Intended Use

The SpineAssist System 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.

The Hover-T Bridge accessory used in conjunction with the SpineAssist device for minimally invasive surgical procedures, is intended for use for lumbar spinal fusion stabilization surgery.

5. Description of the Device

The SpineAssist device developed by Mazor Surgical Technologies is an accurate image-guided positioning system that extends surgical capability in terms of precision, miniaturization and accessibility. The SpineAssist surgical positioning system assists the surgeon in the operating room to accurately position hand held surgical tools according to a computerized image-based pre-operative plan and to accurately guide surgical tools 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 the Hover-T kit, a special bone attachment component, 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.

6. Technological Characteristics Compared to Predicate Device

The technological characteristics of the modified device, 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 device cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2005

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: K051676
Trade/Device Name: SpineAssist Device
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: II
Product Code: HAW
Dated: August 18, 2005
Received: August 29, 2005

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 (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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

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

Enclosure

Appendix A:

Indications for Use Statement

510(k) Number (if known): K 051676

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.

The Hover-T Bridge accessory used in conjunction with the SpineAssist device for minimally invasive surgical procedures, is intended for use for lumbar spinal fusion stabilization surgery.

Prescription Use √ (Per 21 C.F.R. 801.109) OR Over-The-Counter Use ____ (Optional Format 1-2-96)

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

K051676 Barbara Richards Br MYM

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

510(k) Number K051676