SECTION 7 - SUMMARY OF SAFETY AND EFFECTIVENESS

K102130
(Premarket Notification [510(k)] Number)

AUG 26 2010

1. Submitter Information

Manufacturer Name & Address
Mazor Surgical Technologies Ltd.
7 HaEshel Str.
P.O.B. 3104
Southern Caesarea Industrial Park, 38900
ISRAEL

Official Correspondent
Ahava Stein
A. Stein – Regulatory Affairs Consulting
20 Hata'as St.
Kfar Saba 44425
Israel

2. Date Prepare: July 2010

3. Device Name

Proprietary Name: TenZing System

Common / Usual Name: Combination of:
1. Spinal Stereotaxic instrument; and
2. 3-D Reconstruction Tool for Mobile X-Ray Devices

FDA Classification Name:
1. 21 CFR 882.4560; Stereotaxic instrument with product code HAW.
2. 21 CFR 892.2050; System, image Processing, Radiological and product code LLZ.

FDA Classification: Class II, Product Code HAW and LLZ

4. Predicate Devices

The TenZing System is substantially equivalent to the following devices

Manufacturer	Device	510(k)	Date Cleared
Mazor Surgical Technologies	SpineAssist	K073467	05/23/2008
Mazor Surgical Technologies	C-InSight	K081672	08/15/2008

5. Device Description

The TenZing system is a device modification of the SpineAssist system, designed to incorporate both the original SpineAssist system and the C-InSight system in one workstation. The TenZing console is identical to the SpineAssist console. The system is intended to be used in a variety of hospital locations (e.g., OR, trauma unit, etc.).

The main components of the TenZing System include:

A. Workstation

B. SpineAssist accessories:
   - Surgical Accessories Kit
   - Setup Kit

C. SpineAssist Device

D. C-InSight accessories:
   - Spine Target Kit
   - Extremities Target Kit

E. Image Adaptor

F. Spine Assist Disposable kits

G. C-InSight Sterile Sheath Disposable kits

6. Intended Use / Indications

The TenZing System is a combination of the SpineAssist System and C-InSight System, allowing the C-InSight application to run on the SpineAssist Workstation:

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.

The C-InSight software provides a processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects particularly in orthopedic applications.

7. Performance Standards

There are no performance standards under the Federal Food, Drug and Cosmetic Act, for the TenZing device.

8. Performance Testing

The TenZing System software was subject to software validation testing in accordance with the FDA Guidance for the Premarket Submissions for Software Contained in Medical Devices (January 11, 2002).

9. 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 TenZing device are substantially equivalent to the predicate device cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mazor Surgical Technologies, Ltd.
% Ms. Ahava Stein
Consultant
A. Stein-Regulatory Affairs Consulting
20 Hata'as*St. (POB 124)
Kafr Saba, 44425
ISRAEL

AUG 26 2010

Re: K102130
Trade/Device Name: TenZing System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW and LLZ
Dated: July 27, 2010
Received: July 29, 2010

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K102130

Indications for Use

510(k) Number (if known): K102130

Device Name: TenZing System

Indications for Use:

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It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects, particularly for orthopedic applications.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102130

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: May 31, 2007.
See OMB Statement on page 5.

of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
July 27, 2010	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☒ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Mazor Surgical Technologies Ltd.		Establishment Registration Number *(if known)*: 3005075696	
Division Name *(if applicable)*: N.A.		Phone Number *(including area code)*: (972) 4-6270171	
Street Address: P.O.B 3104 Southern Caesarea Park		FAX Number *(including area code)*: (972) 4-6377234	
City: Caesarea	State / Province:	ZIP/Postal Code: 38900	Country: Israel
Contact Name: Armin Schneier			
Contact Title: QA & Regulatory Manager		Contact E-mail Address: armin@mazorst.com	

SECTION C APPLICATION CORRESPONDENT (e.g. consultant, if different from above)

Company / Institution Name: A. Stein – Regulatory Affairs Consulting			
Division Name *(if applicable)*: N.A.		Phone Number *(including area code)*: (+972) 9-7670002	
Street Address: 20 Hata'as St. (POB 124)		FAX Number *(including area code)*: (+972) 9-7668534	
City: Kfar Saba	State / Province:	ZIP/Postal Code: 44425	Country: Israel
Contact Name: Ahava Stein			
Contact Title: Consultant		Contact E-mail Address: ahava@asteinrac.com	

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SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Response to FDA correspondence:
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access
- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final
- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing
- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☒ Other Reason *(specify)*: *Modified Device*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	HAW	2	LLZ	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K073467	SpineAssist Device	Mazor Surgical Technologies
2	K081672	C-InSight System	Mazor Surgical Technologies
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

a) Spinal Stereotaxic Instrument

b) 3-D Reconstruction Tool for Mobile X-Ray Devices

	rade or Proprietary or Model Name for This Device		Model Number
1	TenZing (a.k.a. Spine Theater)	1	N/A
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
HAW, LLZ	§882.4560, §892.2050	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel: Neurology, Radiology

Indications *(from labeling)*

The TenZing System is a combination of the SpineAssist System and C-InSight System, allowing the C-InSight application to run on the SpineAssist Workstation:

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.

C-InSight software provides a processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image. It is ıded to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects, particularly for orthopedic ąplications.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	FDA Establishment Registration Number: 3005075696	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name: Mazor Surgical Technologies Ltd.		Establishment Registration Number: 3005075696	
Division Name *(if applicable)*: N.A.		Phone Number *(including area code)*: (972) 4-6270171	
Street Address: P.O.B 3104 Southern Caesarea Park		FAX Number *(including area code)*: (972) 4-6377234	
City: Caesarea	State / Province:	ZIP/Postal Code: 38900	Country: Israel
Contact Name: Armin Schneier	Contact Title: QA & Regulatory Manager	Contact E-mail Address: armin@mazorst.com	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number:	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name:		Establishment Registration Number:	
Division Name *(if applicable)*:		Phone Number *(including area code)*:	
ɔɑt Address:		FAX Number *(including area code)*:	
City:	State / Province:	ZIP/Postal Code:	Country:
Contact Name:	Contact Title:	Contact E-mail Address:	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number:	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name:		Establishment Registration Number:	
Division Name *(if applicable)*:		Phone Number *(including area code)*: ( )	
Street Address:		FAX Number *(including area code)*: ( )	
City:	State / Province:	ZIP/Postal Code:	Country:
Contact Name:	Contact Title:	Contact E-mail Address:	

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* ıment.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601-1	IEC	Medical electrical equipment - part 1: general requirements for safety 1: collateral standard: safety requirements for medical electrical systems	1988 +1990 + Amendments	
2	60601-1-2	IEC	Medical Electrical Equipment, Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests	2007	
3					
4					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

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MAZOR
Surgical Technologies

System/Software Test Results (STR) for

SpineAssist Version (b)(4)

Document information:

Project Name	SpineAssist
Project Number	(b)(4)
Document No.	

Revision History:

Date	Revision Level	Author	ECO No.	Change Description
27.01.2010	(b)(4)	(b)(4)	(b)(4)	(b)(4)
24.08.2009	(b)(4)	(b)(4)	(b)(4)	

Approvals:

(b)(4)

CONFIDENTIAL for internal use only

(b)(4)

(b)(4)

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(b)(4)

SECTION 6 – TRUTHFUL AND ACCURATE STATEMENT

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

(As Required by 21 CFR 807.87 (j))

I certify that, in my capacity as QA & Regulatory Affairs Manager of Mazor Surgical Technologies, Ltd., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b)(6)

Signature

Mr. Armin Schneier,
QA & Regulatory Affairs Manager

Typed Name and Title

Mazor Surgical Technologies, Ltd.

Company

July 1, 2010

Date

496

SECTION 1 - INDICATIONS FOR USE

510(k) Number (if known):_____

Device Name: TenZing System

Intended Use Statement:

The TenZing System is a combination of the SpineAssist System and C-InSight System, allowing the C-InSight application to run on the SpineAssist Workstation:

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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)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mazor Surgical Technologies, Ltd.
% Ms. Ahava Stein
Consultant
A. Stein-Regulatory Affairs Consulting
20 Hata'as*St. (POB 124)
Kafr Saba, 44425
ISRAEL

AUG 26 2010

Re: K102130
Trade/Device Name: TenZing System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW and LLZ
Dated: July 27, 2010
Received: July 29, 2010

Dear Ms. Stein:

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Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

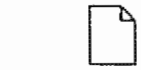
Enclosure

SECTION 4 – PRODUCT LABELING

This section includes the proposed product labeling for the TenZing system. This section includes the TenZing User Guide (provided in Appendix 4-1), TenZing System Brochure (provided in Appendix 4-2), and the device package labels (provided in Appendix 4-3).

APPENDIX 4-1

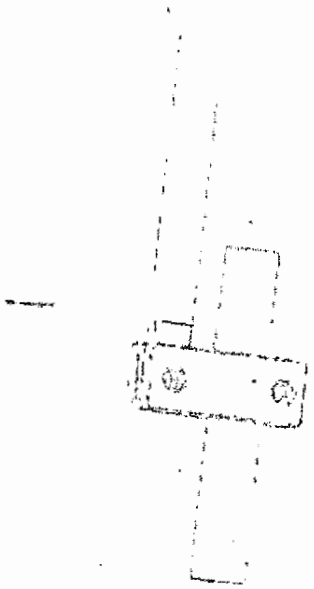
TENZING USER GUIDE



Imagine the Difference

Mazor Surgical Technologies

TenZing
User Guide



Revision A

Caution:
US Federal Law restricts this device to sale by or on the order of a physician.

Contact Information

MAZOR Surgical Technologies Ltd.
P.O.B 3104 Southern Caesarea Park 38900 Israel
Telephone:972-(0)4-6270171
Fax: 972-(0)4-6377234
e-mail: support@mazorst.com
Website: www.mazorst.com

MAZOR Surgical Technologies Inc.
4361 Shackleford Road
Norcross, GA 300093
Telephone: (770) 564-5790
Fax: (770) 564-5791
Toll Free: (800) 70-MAZOR
e-mail: usa@mazorst.com
Website: www.mazorst.com

Authorized Representative in Europe:
MEDNET GmbH
Borkstrasse 10,
48163 Muenster, Germany
Telephone: +49 251 32266-0
Fax: +49 251 32266-22
Website: www.medneteurope.com; **e-mail:** info@medneteurope.com
For additional marketing information: info@mazorst.com
Website: www.mazorst.com
Service: support@mazorst.com

Table of Contents

Preface

The Preface contains the following information relating to the use of the TenZing system:

- Conventions Used in this Manual
- Safety Warning and Compliance Labels

Conventions Used in this Manual

To enhance readability, emphasized text and graphic symbols are used to identify important *Warnings*, *Cautions*, *Procedure Instructions* and special *Notes*. Examples of these elements are shown below:

Points of Emphasis

Italic or **bold** text denotes points of emphasis.

Warnings

Warnings *provide important information and are used to identify conditions or actions, which will result in equipment damage if the instructions are ignored. These are set off by horizontal bars, and are accompanied by the warning graphic in the margin.*

Cautions

Cautions *are used to identify conditions or actions that may result in equipment damage or malfunction if the instructions are ignored. These are set off by horizontal bars, and are accompanied by the caution graphic in the margin.*

Notes

Two types of notes are used in the manual to identify *mandatory* and *general* information, as shown in the examples below.

Mandatory notes are used to identify procedures that must be performed to ensure normal or optimal system performance. These are set off by horizontal bars, and are accompanied by the mandatory note graphic in the margin.

General notes provide non-mandatory information as a general guide to the user. These are set off by horizontal bars, and are accompanied by the general note graphic in the margin.

Illustrations

The graphics and drawings provided in this manual are for the purposes of illustration and reference only. The specifications on which they are based are subject to change without notice.

Procedure Instructions

Procedures are numbered and accompanied by the steps graphic in the margin. For example:

Follow these steps to open a file:

1. Select **Open** from the *File* menu.
2. Navigate to the file to open and select it.
3. Click **OK**.

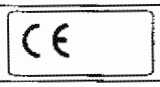
Help

A **Help** button has been provided on all screens (located on the right of the instruction line). This enables the user to access on the system *User Guide*, if required.

Holding the mouse cursor over the button evokes the display of a hint window with the message: *Open the User Manual on the relevant page.*

Safety Warning and Compliance Labels

The *TenZing* system is fitted with safety warning and compliance labels. These are adhered to the Workstation rear panel. For a definition of individual symbols, see below.

Symbol	Definition
	Identifies degree of protection against electric shock. Class I - Type B applied equipment enclosed
	Warning! Electric Shock Hazard High Voltage present in equipment Do not remove cover. Refer servicing to qualified servicing personnel.
	Caution! Consult accompanying documents for safety instructions.
	Danger! Equipment not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE with AIR or with OXYGEN OR NITROUS OXIDE.
	CE Certification Mark
	Waste Electrical and Electronic Equipment (WEEE) Disposal This symbol indicates that waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

Warnings

Warnings *Use of the TenZing system requires the user to observe the warnings detailed below:*

- The *TenZing* system should only be used by qualified, medical professionals who have been thoroughly trained and qualified to use the system.
- Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 60601-1-1 for medical equipment). Furthermore, all configurations must comply with the system standard IEC 60601-1-1. With the exception of the connection to the fluoro imaging system or the removable data media (CD or DOK), no other devices should be connected to the *TenZing* .
- The *TenZing* system is not suitable for use in the presence of a flammable, anesthetic mixture containing: air, oxygen or nitrous oxide. Position the *TenZing* system at least 25cm (10 in) from any source of flammable gas.
- Warning on electromagnetic or other types of interference:
  The *TenZing* system has been tested according to EN 60601-1-2 standards and is therefore suitable for work in a surgical room environment where the other equipment has also been tested accordingly.

Cautions

Cautions *Use of the TenZing system requires the user to comply with the following precautionary instructions:*

The system has been tested with an external UPS. The system should be powered by an equivalent UPS system with the following ratings:

- Power: 1000VA
- Input voltage: 115/230V AC
- Frequency: 50/60Hz with surge protection
- Compliance with standard: EN 55022-B (for UPS only)
- Before moving the *TenZing* system from room to room, shut down power to the system, disconnect and store all cables.
- The *TenZing* system has been tested and found suitable for use in the following countries:

  United States and Japan: 110-120 V AC, 5.0 Amps at 60 Hz
  Outside the U.S. and Japan: 220-240 V AC, 2.5 Amps at 50 Hz

Warnings *Current that exceeds these ratings will overload the isolation transformer, causing a serious safety hazard, which could result in explosion, fire, and/or irreparable damage to the system!*

- The *TenZing* system contains no user-repairable parts. For repair or replacement of any part of the system, contact Mazor Surgical Technologies technical support.

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Chapter 1

System Overview

This chapter contains a general overview of the TenZing system and provides information on the following:

- About the TenZing System
- Features and Benefits of the TenZing System
- Indications for Use
- TenZing Components

About the TenZing System

TenZing is a software product, combines two of Mazor Surgical Technologies' capabilities: the SpineAssist and the C-InSight.

The SpineAssist application enables the surgeon to plan and execute screws or any other trajectories insertion to vertebrae. This goal is achieved by pre-operation planning of the implant (for example screw) insertion on CT data. During the operation the planned positions are located and projected on Fluoro image relative to the robot position while the robot is then guided to the actual position.

The C-InSight application is a software based product, which converts a sequence of Two-dimensional fluoroscopy images into a 3D volume, intraoperatively.
The C-InSight computer is connected to a traditional C-Arm in the operation room and grabs all images from the C-Arm. Using a tracking algorithm, the C-InSight software is able to convert a continues scan around the region of interest into a 3D image intra-operatively.

The *TenZing* is a workstation which contains all C-InSight and SpineAssist components. This allows the physician to perform SpineAssist procedures and C-InSight procedures as independent applications, as we know it today. Farther more, the *TenZing* allows the surgeon to perform SpineAssist procedure and get an intra-operative 3D verification using the C-InSight application. That way, the surgeon can get a real time feedback regarding implants positioning.

The TenZing User Guide is supplementary to the SpineAssist User Manual and the C-InSight User Manual. For detailed information and operating instructions, refer to the appropriate User Manual.

Features and Benefits of the TenZing System

Both SpineAssist® and C-InSight™ create an Enhanced Synergy:

- Enable an extremely accurate execution
- Optimize Surgical Outcomes
- Reduce exposure to harmful X-ray radiation
- Simplifies complex procedures
- Immediate 3D images from existing OR C-Arm equipment

Indications for Use

The TenZing System is a combination of the SpineAssist System and C-InSight System, allowing the C-InSight application to run on the SpineAssist Workstation.

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.

The C-InSight software provides a processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image .
It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects, particularly for orthopedic applications.

TenZing Components

The TenZing main components, basic and optional accessories are described below.
Note that the some parts are applicative and configured for independent sale and operation

The main components of the TenZing System include:

A. Workstation
B. SpineAssist accessories:
   - Surgical Accessories Kit
   - Setup Kit
C. SpineAssist Device
D. C-InSight accessories:
   - Spine Target Kit
   - Extremities Target Kit
E. Image Adaptor
F. SpineAssist Disposable kits
G. C-InSight Sterile Sheath Disposable kits

All accessories are exactly the same as in the SpineAssist device and the C-InSight device, described in the independent User Manuals

For part numbers, refer to Appendix A.

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Workstation (WS)

The TenZing workstation is based on the dedicated SpineAssist Workstation console.

The workstation contains the following items:

- Touch Screen
- Keyboard and mouse
- SpineAssist Device
- Computer (see hardware requirements)
- PDU
- Controller
- DVD drive
- Image Adaptor
- Storage Compartment

The Workstation computer controls all processing and has a Video-In signal connection. The C-Arm transmits the fluoroscopic images to the computer via the Video-In signal, where they are processed and reconstructed.

Side and rear views of the TenZing WS are illustrated in Figure 1 and Figure 2 respectively.

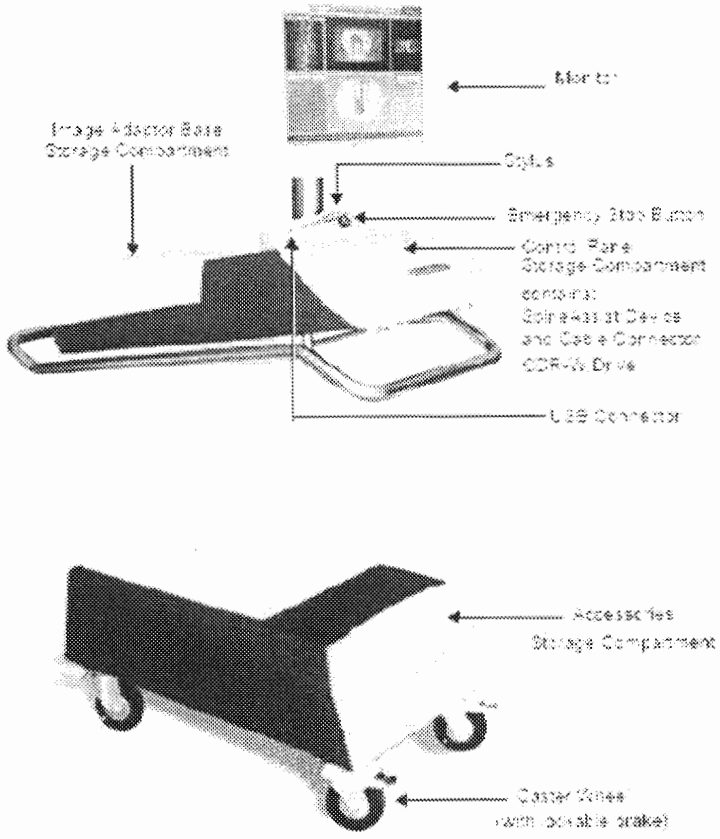

Figure 1: TenZing-Workstation (WS) - Side View

G3

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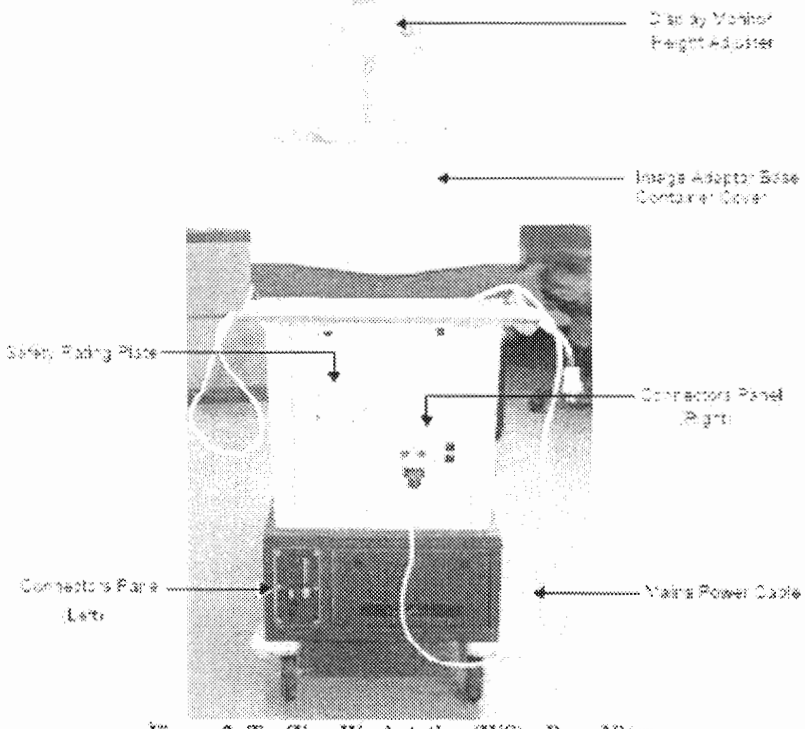

Figure 2: TenZing Workstation (WS) - Rear View

The Workstation provides the user a manual control panel on the front to access basic operations such as:

- DVD
- USB connector - for the Disk-on-key (DOK) removable storage media

Image Adaptor

The *TenZing* Image Adaptor (see Figure 3) is constructed from two rounds, plastic plates with embedded, molten bead patterns. It is attached to the C-Arm's Image Intensifier prior to the calibration process, and it remains attached throughout the calibration and during the scanning.

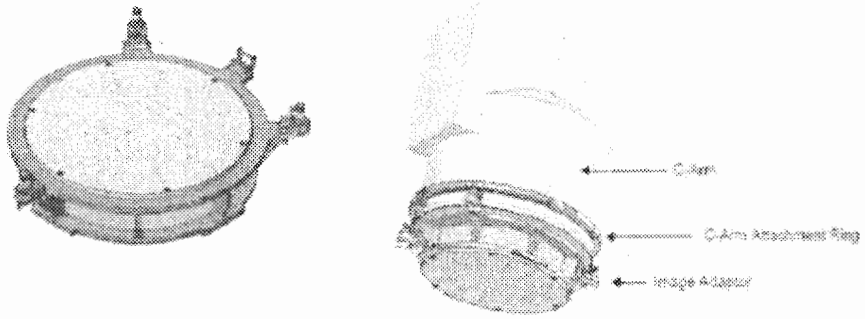

Figure 3: TenZing Image Adaptor

Note:
The *TenZing* Image Adaptor is identical to the SpineAssist Image Adaptor (see "SpineAssist User Guide")

Workstation Installation

The *TenZing* software (either SpineAssist or C-InSight applications) comes pre-installed and factory-validated.

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Chapter 2

Getting Started

This chapter outlines the procedures required to get started using the TenZing system and also contains general information regarding the following:

- Overview of Procedure Stages
- SpineAssist Procedure
- C-InSight Procedure
- Intra-operative Verification

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Overview of Procedure Stages

The *TenZing* system allows the user to use the known SpineAssist and C-InSight applications from the same workstation
Additionally, the *TenZing* allows the user to perform C-InSight 3D scans during SpineAssist procedure, to get better evaluation regarding the spine surgical procedure

SpineAssist Procedure

The SpineAssist application allows user to place and find trajectories over patient's spine, according to pre-operative planning.
The system helps the surgeon to execute his planning with high accuracy and in simplicity.

The SpineAssist Procedure includes the following steps:

- Setup
- Planning
- operation

All SpineAssist stages and capabilities are described in the SpineAssist User Manual.
For further SpineAssist information, refer to SpineAssist User Manual.

C-InSight Procedure

The C-InSight application allows the surgeon to get real time 3D view of anatomy.
During operation, surgeon is able to perform C-InSight scan, using a standard C-Arm.
The C-InSight software converts the C-Arm data into 3D slices, which surgeon can view and manipulate in the C-InSight viewer.

The C-InSight Procedure includes the following steps:

- Setup
- Scan
- View

All C-InSight stages and capabilities are described in the C-InSight User Manual.
For further SpineAssist information, refer to C-InSight User Manual.

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Intra-operative Verification

The *TenZing* allows the user to combine the SpineAssist and C-InSight applications in order to increase clinical benefit.
By performing intra-operative C-InSight scan during SpineAssist procedure, user can verify implants location.

Intra-operative verification contains the following steps:

- SpineAssist System Setup
- SpineAssist Planning
- SpineAssist Operation
- C-InSight Scan
- C-InSight View

System Setup Procedure

The system setup procedure is performed by an OR team member to prepare the *TenZing* system for the SpineAssist and C-InSight procedures.

For detailed instructions on SpineAssist Setup Procedure, refer to the information provided in SpineAssist User Manual.

Planning Procedure

The planning procedure is performed by the clinician pre-operatively. The planning procedure is part of the SpineAssist Application

For detailed instructions on SpineAssist Planning Procedure, refer to the information provided in SpineAssist User Manual.

Operation Procedure

The operation procedure is performed in the OR. The operation is part of the SpineAssist procedure.
During operation, clinician executes his pre-operative planning, using the SpineAssist Device.
In the TenZing System, clinician is able to perform intra-operative 3D scan, using C-InSight capabilities.

For detailed instructions on SpineAssist Operation Procedure, refer to the information provided in SpineAssist User Manual.

Scanning Procedure

The scanning procedure is performed in the OR and is part from the C-InSight application.
Whenever clinician feels that he will get a benefit from intra-operative 3D scan, he is able to open the C-InSight application and to scan the patient.
In time of 2 minutes, clinician will be able to view the 3D results.
To go back to the SpineAssist Operation, clinician clicks a button and continues from where he stopped.

3D intra-operative scan is available during the whole SpineAssist operation procedure and can be repeated.

For detailed instructions on performing this intra-operative Scanning Procedure, refer to the information provided in C-InSight User Manual.

Viewing Procedure

C-InSight viewer provides the user to view and manipulate the 3D reconstructed volume.
At the moment the image processing is done, the application uploads automatically the C-InSight viewer.
User is able to go back to SpineAssist Operation procedure any time.

For detailed instructions on C-InSight Viewer, refer to the information provided in C-InSight User Manual.

Chapter 3

Performing Intra-Operative Verification

This chapter describes and explains the TenZing system Intra-operative verification, as follows:

Overview

Accessing the TenZing System

Performing Intra-operative Verification scan

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Overview

Set up of the *TenZing* system must be performed prior to the scan procedure. Although tuning was performed when the system was installed, a few additional procedures are required immediately prior to the scan.

See **Figure 4**, for a diagram of the *TenZing* system connections required to setup and work with the C-Arm fluoroscope equipment.

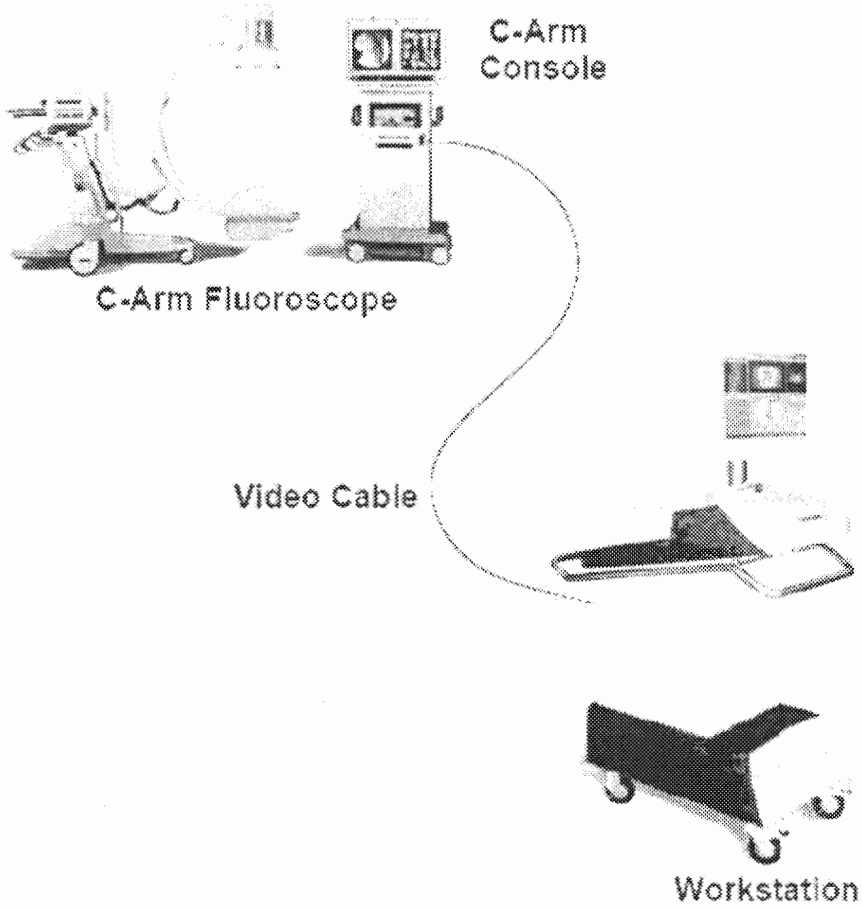

Figure 4: TenZing connection diagram

The *TenZing* Workstation has a control panel on the front (monitor, keyboard and mouse); other controls provide the user with to access basic operations such as:

- ON/OFF button.
- CDR-W drive
- USB port - for Disk-on-key (DOK) removable storage media.

Accessing the TenZing System

To access the TenZing Application:

1. Turn on the *TenZing* workstation; the software will be uploaded automatically
2. When prompted, type the **User Name** and **Password** in the Login screen:

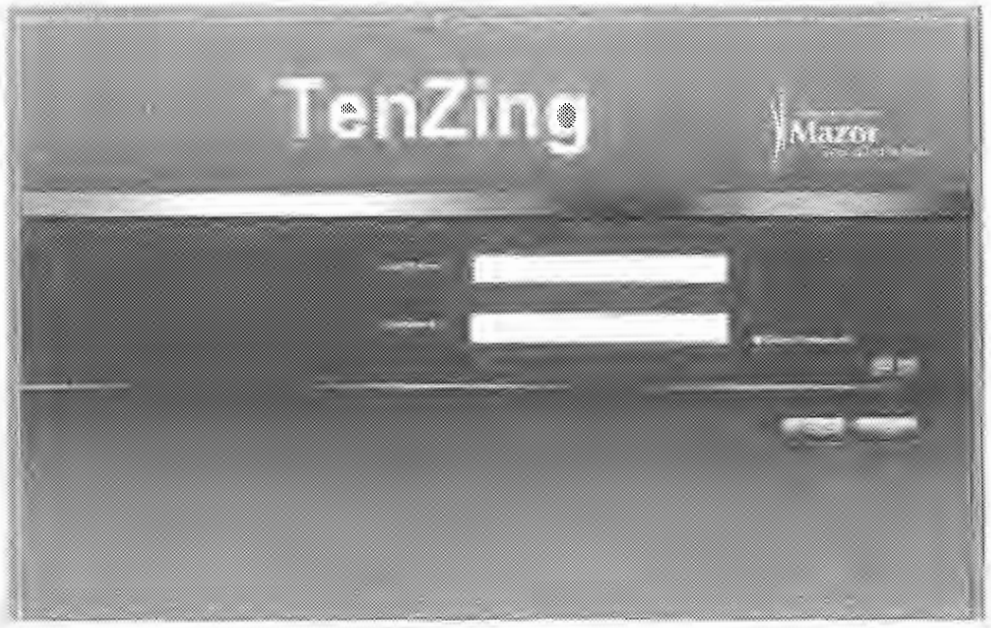

Figure 5: TenZing Login screen

Use the keyboard for typing; alternatively use the on-screen "virtual keyboard" -
Click in the User Login Name field, and then click the keyboard icon located on the right side of the message bar.

3. Click .

The *TenZing* 'Choose Application' window opens, as shown in **Figure 6**

Figure 6: 'Choose Application' screen

4. Choose the desired application, either SpineAssist or C-InSight.

In the *TenZing* System, the SpineAssist and C-InSight can function as independent applications.

In order to perform C-InSight scan, click on the C-InSight button

For detailed instructions C-InSight Procedure, refer to the information provided in C-InSight User Manual.

In Order to perform SpineAssist procedure, click on the SpineAssist button.

For detailed instructions on SpineAssist Procedure, refer to the information provided in SpineAssist User Manual.

For intra-operative verification, choose "SpineAssist" option

The SpineAssist main window will open. Follow the User Manual instructions for Setup, Planning and Operation.

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Performing Intra-operative Verification scan

1. Perform SpineAssist procedure, as described at the SpineAssist User Manual
2. At any moment, during SpineAssist Operation stage, user is able to perform intra-operative verification

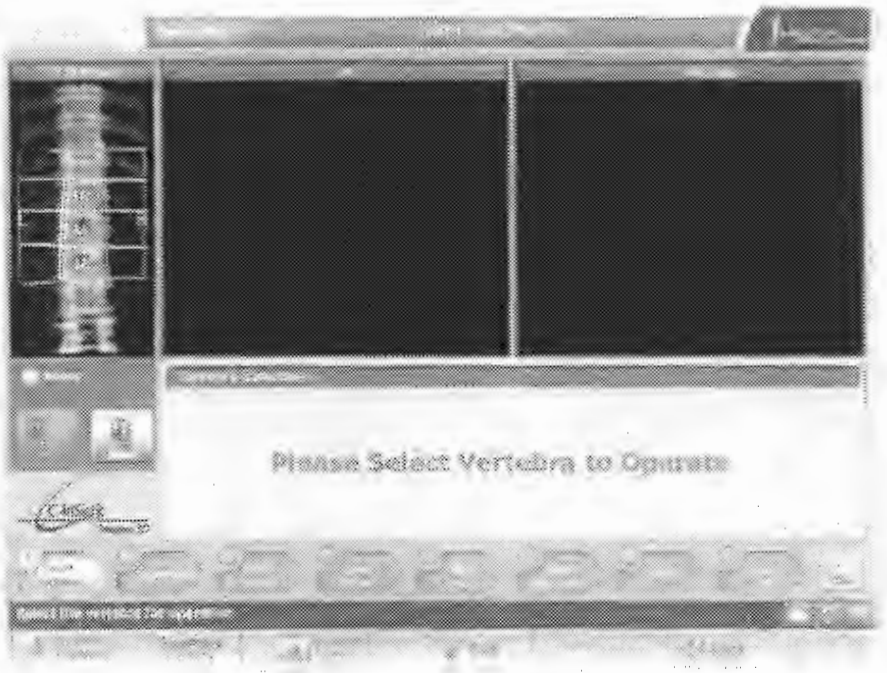

Figure 7: SpineAssist Operation Screen

3. To perform a scan, click on  button.
4. The application will direct you to the C-InSight Main Screen, as described in the Image bellow.

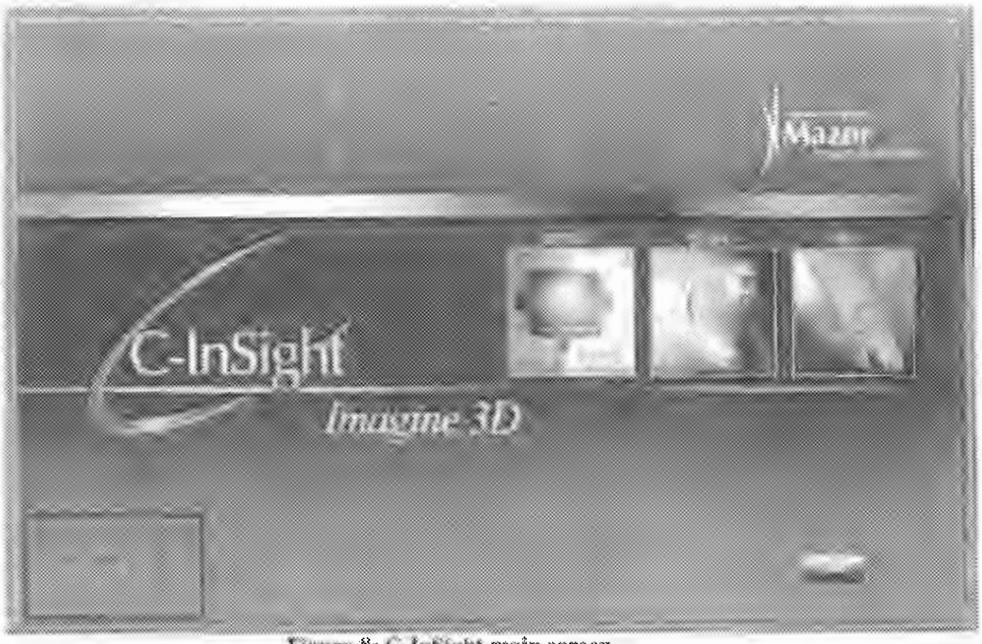

Figure 8: C-InSight main screen

5. If you need to re-calibrate the C-Arm, click on **Setup** button

Re-Calibration is needed if the C-Arm Image Adaptor position was changed.

6. for scanning, click on **Scan** button
7. Perform C-InSight scan according to the direction in the C-InSight User Manual
8. After the C-InSight application will process the image data, the 3D volume will be presented over the C-InSight Viewer
9. To control the C-InSight Viewer, refer to the C-InSight User Manual

In all C-InSight stages, user is able to go back to SpineAssist procedure to the point where he left it.

10. To go back to SpineAssist Operation procedure, click on  button.

Appendix A

TenZing Components

Appendix A describes and explains the TenZing external main components

TenZing Main Components

Part	Part Number
SpineAssist Workstation	TPL0001-04

Part	Part Number
Surgical Accessories Kit	KIT0156-01
Setup Kit	KIT0080-01

Part	Part Number
SpineAssist Device	ASM0075-02

Part	Part Number
SpineAssist Device	ASM0075-02

Part	Part Number
Spine Target Kit	KIT0130-01
Extremities Target Kit	KIT0131-01

Part	Part Number
Image Adaptor	KIT0181-01

Part	Part Number
Bed Mount Disposable Kit	KIT0105-01
Clamp Disposable Kit	KIT0109-01
Minimally Invasive Disposable Kit	KIT0110-01
Thoracic Clamp Disposable Kit	KIT0112-01

Part	Part Number
C-InSight Sterile Sheath Spine	KIT0102-01
C-InSight Sterile Sheath Extremities	KIT0190-01

Appendix B

Troubleshooting

Appendix B describes and explains the easy steps required for troubleshooting the system.

System Troubleshooting

The TenZing system is a combination of C-InSight and SpineAssist applications.

All SpineAssist and C-InSight messages are relevant and described in the specific user manual.

In the SpineAssist and C-InSight user manuals user will find instructions to handle the following situations:

SpineAssist troubleshooting –

- General
- Planning
- Operation setup
- Operating room – general messages
- Acquisition in the operating room
- Registration
- Setup
- Operating room – MSG device

C-InSight troubleshooting –

- General Messages
- Operation Setup
- Operating Room
- Managing Data
- Utilities

Appendix C

License and Warranty Information

Appendix C describes and explains the TenZing system with regard to General Terms and Conditions

License and Warranty Information

ARTICLE 1 – SUMMARY

These General Terms and Conditions are entered into between Mazor Surgical Technologies ("Mazor", "we", "us", or "our"), an Israeli company, having a principal place of business of in Ceasarea Israel and the company, hospital, center, or corporation identified above ("Customer", "you", or "your").

The purpose of these General Terms and Conditions is to set forth the general terms and conditions that will apply to all services performed by Mazor and all products sold or licensed by Mazor to you. The specific terms and conditions on which such services and products will be provided will be set forth in one or more separate Purchase Order Form(s).

The provisions of these General Terms and Conditions shall automatically be incorporated into each Purchase Order Form, unless otherwise expressly set forth therein. In the event of a specific conflict between the provisions of these General Terms and Conditions and provisions of any Purchase Order Form, these General Terms and Conditions shall control.

ARTICLE 2 –CERTAIN DEFINITIONS

As used herein, the following terms shall have the following meanings:
"Affiliates" means subsidiaries of Mazor and/or its parent company, Mazor Surgical Technologies Ltd. "Documentation" means the installation instructions and user manuals supplied to Customer by Mazor pertaining to the operation of the Integrated System.
"Effective Date" means the date that the parties enter into these General Terms and Conditions as evidenced by the last date set forth in the signature blocks below or as set forth in the applicable Purchase
Order Form.
"Integrated System" means the integrated system specified in the Purchase Order Form, including, without limitation, the TenZing , Mazor Software, the Third-Party Software and the Related Products.
"Installation Site" means the location(s) or Customer's address specified in the Purchase Order Form to where the Integrated System will be delivered and where it will be assembled and installed in accordance with the terms of this Agreement.
"Licensed Software" means, collectively, the Mazor Software and the Third-Party Software.
"Mazor Software" means (i) the object code form of the Mazor software applications identified in the Purchase Order Form and provided to Customer by Mazor hereunder; (ii) the Documentation pertaining thereto; and (iii) any updates, modifications,

maintenance releases, bug fixes or work-arounds to such software that Mazor may provide Customer from time to time.
"Related Products" means kits of disposable clamps, AP and lateral targets, clamping tool and C-Arm calibration phantom.
"Third-Party Software" means (i) any software owned by a person or a company other than Mazor and provided to Customer by Mazor hereunder; (ii) the Documentation pertaining thereto; and (iii) any updates, modifications, maintenance releases, bug fixes or work-arounds to such software that Mazor may provide Customer from time to time.

ARTICLE 3 – PURCHASE AND SALE; LICENSE

3.1 Purchase and Sale of the Integrated System.

Subject to the terms and conditions herein, Mazor hereby agrees to sell, transfer and convey to Customer, and Customer hereby agrees to purchase from Mazor, the TenZing and Related Products, if any, identified on the Purchase Order Form.

3.2 Use of the Licensed Software.

Mazor grants to Customer the following licenses:
(i) A limited, non-exclusive, non-transferable license (without the right to sublicense) to use the Mazor Software solely for Customer's internal business purposes in connection with the operation of the TenZing and Related Products, and subject to the additional restrictions, if any, set forth in the Purchase Order Form; and
(ii) A limited, non-exclusive, non-transferable sublicense (without the right to grant further sublicenses) to use (subject to the additional terms and conditions specified by the owner of such software) the Third-Party Software solely for Customer's internal business purposes in connection with the operation of the TenZing and Related Products, and subject to the additional restrictions, if any, set forth in the Purchase Order Form.
The Licensed Software is provided, and is authorized to be installed, executed, and used, only in machinereadable, object code form.

3.3 Delivery and Installation of the Integrated System.

If so specified on the applicable Order Form, Mazor will use commercially reasonable efforts to deliver, assemble and install the Integrated System at the Installation Site on or before the Installation Date that may be specified in the Purchase Order Form. Mazor will not be responsible for delays in assembly or installation of the Integrated System caused by events or circumstances beyond its reasonable control.

3.4 Registration.

It is Mazor's responsibility to ensure that the TenZing delivered to Customer by Mazor will carry a CE mark and FDA approval.

3.5 Restrictions.

No copying or use of the Licensed Software by Customer other than as expressly authorized by this Agreement is permitted. Without limiting the generality of the foregoing, Customer will not
(i) Reverse engineer, decompile or modify the Licensed Software in any manner, nor will Customer incorporate the Licensed Software, in whole or in part, in any other product, or create derivative works based on the Licensed Software;

(ii) Manufacture, sell or otherwise commercially exploit the Licensed Software, except in support of Customer's own internal business operations; or

(iii) Sublicense, transfer, pledge, lease or rent, or share its rights to the Licensed Software in connection with the operation of the TenZing and Related Products.
Customer shall not remove any copyright, trademark, proprietary rights, disclaimer or warning notice included on or embedded in any part of the Licensed Software.
Customer shall not install the Licensed Software anywhere but the Installation Site without Mazor's prior written consent (which consent shall not be unreasonably withheld); provided, however, that Customer may transfer the Licensed Software to another location temporarily in the event of an interruption of computer operations at the Installation Site.

3.6 No Implied License.

Except for the express license granted herein, no other licenses to the Licensed Software are granted by Mazor by implication, estoppels or otherwise.

ARTICLE 4 – OBLIGATIONS OF CUSTOMER

4.1 Site Preparation.

Customer, at its expense and prior to delivery and installation of the Integrated System at the Installation Site, shall prepare the Installation Site and any required equipment in an appropriate manner and shall cause the Installation Site to conform to any utility, climate control, and communication interface specifications that Mazor or the manufacturers or vendors of the Integrated System may supply

4.2 Inspection of the Integrated System.

If Mazor delivers the Integrated System to the Installation Site, Customer shall promptly inspect the Integrated System upon its arrival at the Installation Site and shall notify Mazor if Customer finds any nonconformity or defect in such Integrated System.

4.3 Installation.

If Mazor installs the Integrated System at the Installation Site, Customer shall provide Mazor with reasonable assistance and access in order that Mazor may install and maintain the Integrated System at the Installation Site.

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ARTICLE 5 – OWNERSHIP

5.1 Licensed Software and TenZing.

As between Customer and Mazor, Mazor and/or its Affiliates and/or its suppliers shall own all right, title and interest in and to the Licensed Software. This Agreement does not transfer or convey to Customer or any third party any right, title or interest in or to the Licensed Software or any associated intellectual property rights, but only a limited right of use revocable in accordance with the terms of this Agreement. Mazor and/or its Affiliates and/or its suppliers is also the sole owner of all intellectual property rights associated with the TenZing and the Related Products.

ARTICLE 6 – INDEMNIFICATION

6.1 Indemnity.

Mazor agrees to defend Customer and pay any final judgment or settlement in connection with any third-party claim based on infringement or misappropriation of U.S. copyrights,
Patents, trade secrets, or other proprietary rights of any third party arising out of Customer's use of the Integrated System.
The foregoing indemnification obligations of Mazor are contingent upon Mazor being promptly notified of such claim, having the sole authority to defend and settle such claim, and receiving the reasonable assistance of Customer in connection therewith at Mazor's expense.

6.2 Right to Procure or Modify.

If a claim of infringement under this Article 7 occurs, or if Mazor determines that a claim is likely to occur, Mazor will have the right, at its sole discretion, to either:

(i) Procure for Customer the right or license to continue to use the Integrated System free of the infringement claim; or
(ii) Modify the Integrated System to make it non-infringing. If these remedies are not reasonably available to Mazor, Mazor may, at its option, terminate this Agreement. In such event, Customer shall return the Integrated System and all related Documentation and material to Mazor, and Mazor shall refund to Customer the then current depreciated value of any TenZing and Related Products. For purposes of this Section 7.2, the depreciation shall be an equal amount per month calculated over a depreciable period of sixty (60) months.

6.3 Indemnity Exclusions.

Notwithstanding the foregoing, Mazor has no obligation with respect to any claim of infringement that is based upon or arises out of:
(i) The use or combination of the Integrated System with any hardware, software, products, data or other materials not specified or provided by Mazor;
(ii) Customer's use of the Integrated System other than in accordance with Documentation or Mazor's written directions or policies; or
(iii) Use of Customer's own equipment.

6.4 Exclusive Remedy.

THE PROVISIONS OF THIS ARTICLE 7 STATE THE SOLE AND EXCLUSIVE OBLIGATIONS AND LIABILITY OF MAZOR AND ITS LICENSORS AND SUPPLIERS FOR ANY PATENT, COPYRIGHT, TRADEMARK, TRADE SECRET OR OTHER INTELLECTUAL PROPERTY RIGHTS INFRINGEMENT ARISING OUT OF OR RELATING TO THE INTEGRATED SYSTEM AND THIS AGREEMENT. THE PROVISIONS OF THIS ARTICLE 7 ARE IN LIEU OF ANY IMPLIED WARRANTIES OF NONINFRINGEMENT, ALL OF WHICH ARE DISCLAIMED.

6.5 Customer Indemnification.

Customer shall indemnify Mazor against any third party claims against Mazor for damages and loses arising out of its use of the Integrated System.

ARTICLE 7 – WARRANTIES AND LIMITATIONS

7.1 Limited Warranty and Disclaimer

7.1.1 TenZing as an Advisor to the Surgeon.

The TenZing was designed to help provide surgeons with more precise and reliable positioning of surgical tools within the spine vertebrae. In no way does the TenZing replace the surgeon.
All decisions during the procedure are to be made solely by the surgeon. At any stage during surgery, the surgeon may reject the TenZing 's counsel and continue the surgery using methods, procedures and devices of the surgeon's choosing. The surgeon should and must reject the advice of TenZing if the surgeon believes, in his/her professional judgment that such course of action is in the best interest of the patient.
It is important to emphasize that the TenZing technology is not capable, designed or meant to alter, replace, modify, override or substitute for in any way the clinical and medical judgment, professional assessment and practical common sense necessarily used by the surgeon who performs the surgery. The product has been developed solely as an advisory system with the inherent and common limitations of advisory systems.

7.1.2 TenZing Warranty.

Mazor warrants that the TenZing will be free from defects in materials and workmanship and that the Mazor Software shall conform in all material respects to any specifications supplied in writing by Mazor (the "Warranty") for a period of twelve (12) months from the date of installation; this Warranty will be in effect only if the Customer sends Mazor the warranty form, signed by the Customer, for the TenZing that was installed at the Installation Site, within 30 days of the date of installation. Mazor's sole responsibility under this Warranty will be to repair or replace, at its option, the TenZing if found to be defective in material or workmanship.
A defective TenZing will be shipped at the Customer's expense to Mazor's repair facility in the United States (Mazor will instruct the exact address as part of the Return Material Authorization ("RMA")), provided however, that prior to such shipment the Customer makes a request for return by contacting Mazor's technical support center requesting a RMA pursuant to a specific form provided to the Customer by Mazor and such RMA is acknowledged by Mazor ("Acknowledged RMA"), which acknowledgement will not be unreasonably withheld. The damaged goods that are covered by an Acknowledged RMA will be repaired or replaced and will be reshipped to the Customer at Mazor's expense.
Any tampering with or modification of the TenZing or any Products related thereto without Mazor's prior written consent will invalidate this Warranty.
This Warranty relates to the TenZing only, and not to any other part of the Integrated System, including but not limited to the Related Products and the Licensed Software.

Mazor's sole obligation and Customer's sole and exclusive remedy, for breach of the foregoing warranty is to repair or replace the TenZing , or, at the discretion of Mazor, to refund all related license and purchase fees paid by Customer.

7.1.3 Conditions Precedent.

Anything herein to the contrary notwithstanding, Mazor shall bear no responsibility for correcting, curing, or otherwise remedying any nonconformity or defect in the Integrated System (or any other breach with respect to the condition or operation of the Integrated
System) if

(1) Customer performs its own installation of the Integrated System and the Integrated
System is not properly installed;

(2) The Integrated System is not maintained and operated under normal conditions by qualified personnel;

(3) The Integrated System incorporates spare or replacement parts or Customer's equipment other than those purchased under this Agreement;

(4) The Integrated System has been altered, abused, misused, or taken apart;

(5) The nonconformity or defect (or other breach with respect to the condition or operation of the Integrated System) has not been reported to Mazor within 30 days after the discovery thereof by Customer; or

(6) The nonconformity or defect (or other breach with respect to the condition or operation of the Integrated System) has arisen as a result of damage to the Integrated System occurring subsequent to delivery thereof to the Installation Site, unless, in any such case, such event or condition directly results from the fault or negligence of Mazor.

7.1.4 Disclaimer.

WITH THE SOLE EXCEPTION OF THE PRECEDING UNDERTAKINGS, TO THE
EXTENT PERMITTED BY APPLICABLE LAW, MAZOR DISCLAIMS ANY AND ALL PROMISES, REPRESENTATIONS, AND WARRANTIES, EXPRESSED OR IMPLIED, WITH RESPECT TO THE INTEGRATED SYSTEM (INCLUDING THE TENZING , THE RELATED PRODUCTS, THE THIRDPARTY SOFTWARE, AND THE MAZOR SOFTWARE) INCLUDING ITS CONDITION, AND THE EXISTENCE OF ANY LATENT OR PATENT DEFECTS. MAZOR AND ITS SUPPLIERS SPECIFICALLY DISCLAIM ANY IMPLIED WARRANTIES OF TITLE, NONINFRINGEMENT, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INTEGRATED SYSTEM. IN ADDITION, MAZOR FURTHER DISCLAIMS ANY AND ALL PROMISES, REPRESENTATIONS, AND WARRANTIES, EXPRESSED OR IMPLIED, WITH RESPECT TO THE NATURE AND QUALITY OF ANY OTHER PERFORMANCE BY MAZOR HEREUNDER.

7.2 Limitation of Liability.

EXCEPT FOR CLAIMS UNDER ARTICLE 7, MAZOR'S LIABILITY FOR ALL CLAIMS ARISING OUT OF THIS AGREEMENT, WHETHER IN CONTRACT, TORT OR OTHERWISE, SHALL BE LIMITED TO THE AMOUNT OF FEES PAID BY CUSTOMER TO MAZOR UNDER THIS AGREEMENT.

7.3 Exclusion of Consequential Damages.

In no event shall Mazor or its affiliates, licensors, or suppliers, be liable to Customer or any third party for any indirect, special, punitive, or consequential damages arising from or in relation to this Agreement or the Integrated System, however caused and regardless of theory of liability, including, without limitation, bodily or personal injury, loss of life, lost profits, costs of delay, any failure of delivery, or liabilities to third parties arising from any source, even if Mazor has been advised of the possibility of such damages.
Except for the express warranties set forth above, Mazor disclaims any other warranty to any Customer or any third party, expressed or implied, including, but not limited to, implied warranties of merchantability and fitness for a particular purpose.
Mazor makes no warranty for any third party products or components (including the Third Party Software and Related Products) that are shipped with, or as part of, the TenZing and/or Integrated System. Such manufacturers may provide their own warranties and/or terms and conditions, if any; and Customer or any third party shall look exclusively to the manufacturer of such products or components in connection with any defect or error related thereto.

ARTICLE 8 - FORCE MAJEURE.

If either party is prevented from performing any of its obligations under this Agreement due to any cause beyond the party's reasonable control, including, without limitation, an act of God, fire, flood, explosion, war, strike, embargo, government regulation, civil or military authority, acts or omissions of carriers, transmitters, providers, vandals, or hackers (a "force majeure event") the time for that party's performance will be extended for the period of the delay or inability to perform due to such occurrence; provided, however, that Customer will not be excused from the payment of any sums of money owed by Customer to Mazor.

ARTICLE 9 – MISCELLANEOUS.

The relationship of Mazor and Customer established by this Agreement is that of independent contractors. Neither party may assign this Agreement, in whole or in part, either voluntarily or by operation of law, without the prior written consent of the other party.

This Agreement is solely for the benefit of the parties and their successors and permitted assigns, and does not confer any rights or remedies on any other person or entity; provided, however, Customer agrees that certain third party suppliers to Mazor are third party beneficiaries to this Agreement, and certain of the provisions hereof are made expressly for the benefit of such suppliers and may be enforceable by such suppliers in addition to Mazor. This Agreement and all aspects of the relationship between the parties shall be governed by the internal laws of the State of New York, exclusive of its conflict of laws principles. The parties consent and agree that the courts of the State of New York are the exclusive forum for litigation of any claim arising under this Agreement.

The application of the United Nations Convention on Contracts for the International Sale of Goods is expressly excluded.

This Agreement and the related Purchase Order Form shall constitute the entire agreement between Mazor and Customer with respect to the subject matter hereof.

No failure of either party to exercise or enforce any of its rights under this Agreement shall act as a waiver of subsequent breaches; and the waiver of any breach shall not act as a waiver of subsequent breaches.

Customer agrees that it will not distribute, transmit, or transfer any copy of the Licensed Software except in compliance with U.S. export laws and regulations. In the event any provision of this Agreement is held by a court of competent jurisdiction to be unenforceable, that provision will be enforced to the maximum extent permissible under applicable law, and the other provisions of this Agreement will remain in full force and effect.

APPENDIX 4-2

TENZING SYSTEM BROCHURE

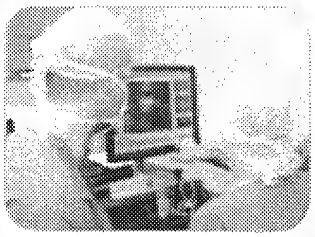
M:\Mazor Robotics\
Spine Theater Special

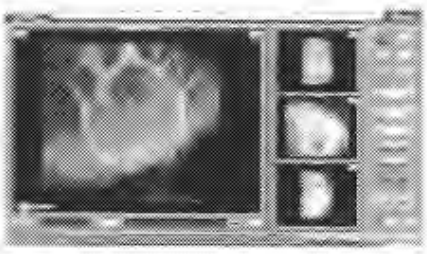
Imagine the Difference

Mazor

Surgical Technologies

TenZing System





You can either build a bigger operation room, or you can benefit the new TenZing

TenZing combines the best of both worlds.

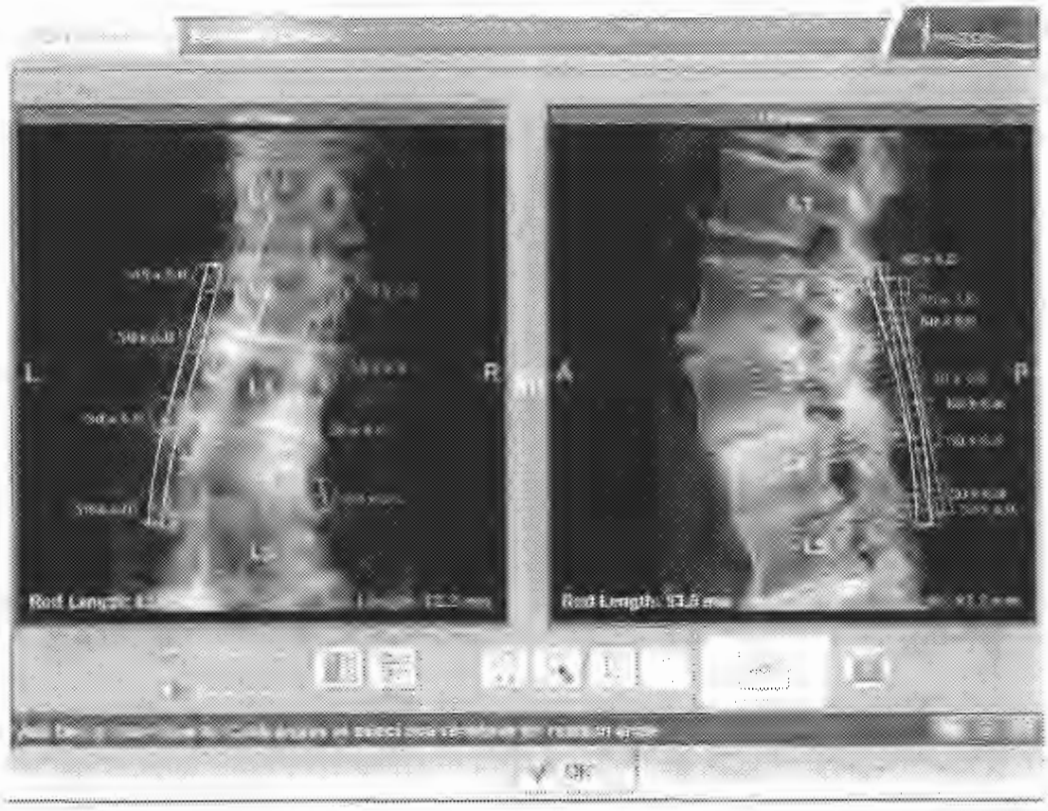
The same workstation runs Mazor's acclaimed SpineAssist® and C-InSight™ allowing surgeons to accurately place implants and view 3-dimensional images in real-time during surgery.

SpineAssist – accuracy and reliability

Supporting a wide variety of procedures, SpineAssist enables you to plan and execute with the highest precision.

Using state of the art planning software, the surgeon can plan in advance the best approach and the required implants. Reducing the possibility of encountering unforeseen anatomic challenges during surgery, the surgeon and the OR team increase their efficiency and satisfaction.

Insensitive to revisions and lack of anatomic landmarks, SpineAssist will guide you towards an accurate execution of the surgery.



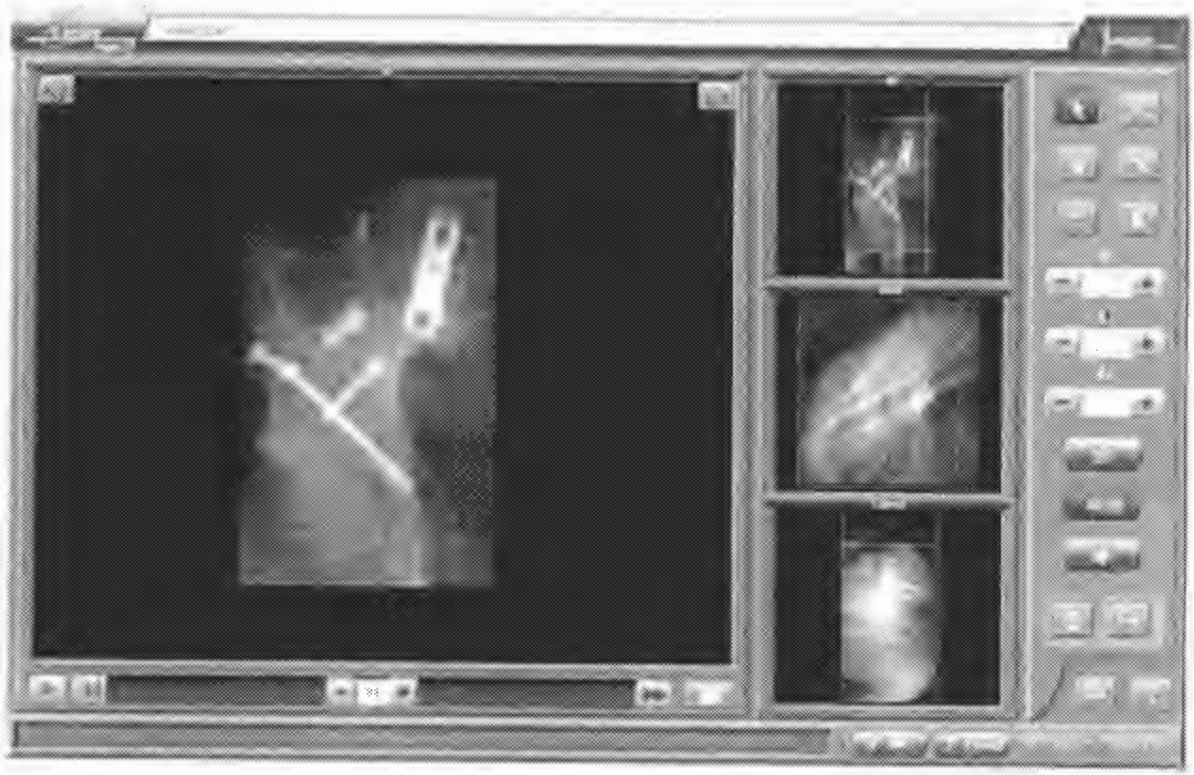
C-InSight - 3D imaging on the fly

2D images cannot provide you with the accurate information regarding fracture reduction and implant placement. Often the patient is returned to surgery for a revision.

Intraoperative 3D imaging can provide the surgeon with the verification and assessment of the surgery's outcome.

C-InSight incorporates state of the art software imaging algorithms to convert 2D images into 3D visualization on the fly.

Using the existing C-Arm and without any preparation, the OR team can create a 3D imaging and slice by slice visualization.



Tenzing – more than the sum of its components

SpineAssist® and C-InSight™ create an Enhanced Synergy:

- Improve Pre-operative planning
- Enable an extremely accurate execution
- Optimize Surgical Outcomes
- Reduce exposure to harmful X-ray radiation
- Simplifies complex procedures
- Immediate 3D images from existing OR C-Arm equipment

Mazor

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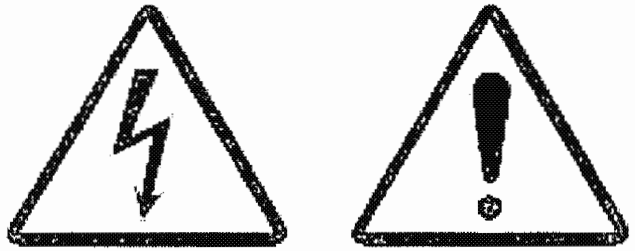
APPENDIX 4-3

PACKAGE AND DEVICE LABEL

M:\Mazor Robotics\
Spine Theater Special



⚠ CAUTION

Electric shock hazard
DO NOT REMOVE COVER
Refer servicing to
Qualified servicing personnel

⚠ DANGER

Equipement not suitable for use in the presense of a FLAMMABLE ANAESTHETIC MIXTURE with AIR or with OXYGEN or NITROUS Oxide.

Imagine the Difference

Mazor
Surgical Technologies

Model TenZing

Serial No.	

Imax	Vnom	Freq.	Pmax
2,5A 5A	230VAC 115VAC	50Hz 60Hz	1000VA

CE 0482 TYPE B

Follow instructions for use

MAZOR Surgical Technologies Ltd. 7 HaEshel St, P.O.Box 3104 Southern Caesarea industrial park, Caesarea 38900, ISRAEL Tel: 972 (0)4 627-0171 Fax: 972 (0)4 637-7234 www.mazorst.com

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APPENDIX 5-1:

DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

Imagine the Difference
Mazor
Surgical Technologies

Declaration of Conformity with Design Controls

Mazor Surgical Technologies Ltd., hereby declares that as required by the risk analysis, all verification and validation activities for the TenZing system were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

Furthermore, Mazor Surgical Technologies Ltd., declares that its manufacturing facility is in conformance with the design control procedure requirements, as specified in 21 CFR 820.30 and the records are available for review, upon request.

(b)(6)

Signature

Mr. Armin Schneier,
QA & Regulatory Affairs Manager

Typed Name and Title

Mazor Surgical Technologies, Ltd.

Company

July 1, 2010

Date

SECTION 2 – DESCRIPTION OF MODIFIED DEVICE

1.1 INTRODUCTION

The TenZing system (a.k.a. Spine Theater or TenZig) is a device modification of the SpineAssist system (K073467), designed to incorporate both the original SpineAssist system (manufactured by Mazor Surgical Technologies Ltd. and cleared under 510(k) No. K073467) and the C-InSight system (manufactured by Mazor Technologies Ltd. and cleared under 510(k) No. K081672) into one workstation.

This Special 510(k) submission describes engineering changes made to combine two of Mazor's FDA cleared devices into a single device providing the features of both original devices. The original devices were not modified, except for the software changes needed to allow simultaneous operation of both devices from a single console. This submission refers in general to the effects of the modifications on the combination of the original devices.

TenZing is a software product, which combines two of Mazor Surgical Technologies' capabilities: the SpineAssist and the C-InSight, both FDA cleared devices.

The SpineAssist application enables the surgeon to precisely position surgical instruments or implants during general spinal surgery. This is achieved through pre-operation planning and virtual placement of the surgical instrument or implant (e.g., a screw) based on the patients' CT data. During the surgical procedure the pre-planned instrument or implant positions are located and projected on Fluoroscopy images relative to the SpineAssist device position while the SpineAssist arm is then guided to the actual position. The SpineAssist is described in previously cleared 510(k) submissions K033413, K051676, K063607 and K073467.

The C-InSight application is a software based product, which converts a sequence of two-dimensional fluoroscopy images into a 3D volumetric image, intraoperatively. The

C-InSight computer is connected to a traditional C-Arm in the operating room and grabs all images from the C-Arm. Using a tracking algorithm, the C-InSight software is able to convert a continuous scan around the region of interest into a 3D image, intra-operatively. The C-InSight is described in the previously cleared 510(k) submission K081672.

The TenZing is a workstation which contains all C-InSight and SpineAssist components. This allows the physician to perform SpineAssist procedures and C-InSight procedures as independent applications, but using the same workstation console. Furthermore, the TenZing allows the surgeon to perform SpineAssist procedures and obtain an intra-operative 3D verification using the C-InSight application. Thus, the surgeon can obtain real time feedback regarding instrument and/or implant positioning.

1.2 GENERAL DEVICE INFORMATION

The TenZing system is a portable console with a few accessories. It comprises the SpineAssist device and the C-InSight device. The TenZing console is identical to the SpineAssist console. The original devices were not modified, except for the software changes needed to allow simultaneous operation from a single console.

This system is intended to be used in a variety of hospital locations (OR, trauma units, etc.), therefore it is designed to be easy for shipping and handling and with the smallest number of external parts and accessories besides the workstation. All external devices have standard storage containers.

The main components of the TenZing System include:

A. Workstation
B. SpineAssist accessories:
   - Surgical Accessories Kit
   - Setup Kit
C. SpineAssist Device
D. C-InSight accessories:
   - Spine Target Kit
   - Extremities Target Kit
E. Image Adaptor
F. Spine Assist Disposable kits
G. C-InSight Sterile Sheath Disposable kits

All afore-mentioned accessories are exactly the same as in the SpineAssist device and the C-InSight device, described in the previously cleared 510(k) submissions K073467 for the SpineAssist and K081672 for the C-InSight.

1.2.1 Workstation Console

The TenZing workstation is based on the dedicated SpineAssist Workstation console. The workstation contains the following items:

- Touch Screen
- Keyboard and mouse
- SpineAssist Device
- Computer (see hardware requirements)
- PDU
- Controller

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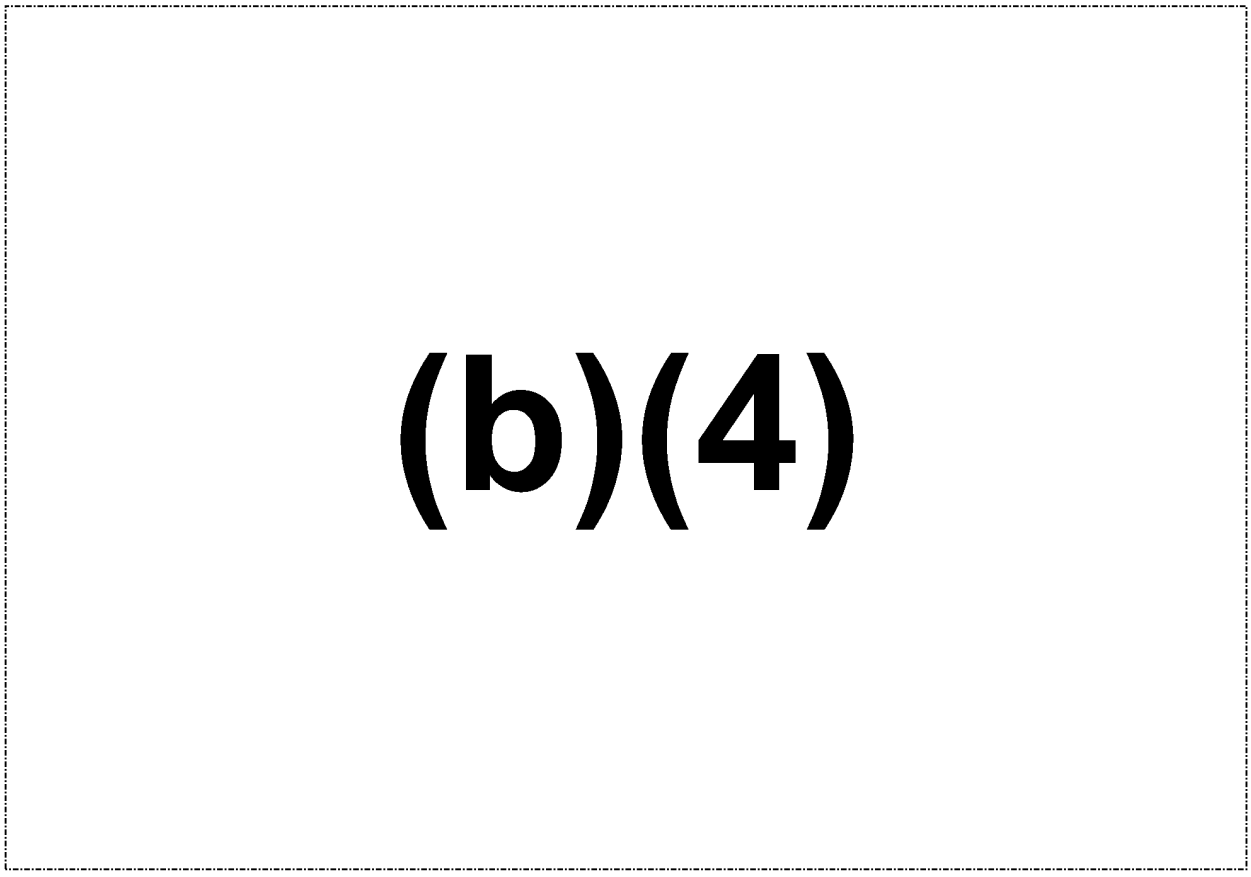
1.2.2 Operator Interface

The TenZing software is installed over the computer and includes the following components:

- TenZing Interface
- SpineAssist Interface
- C-InSight Interface

1.2.3 Applications



1.2.4 Data Management

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1.3 ACCESSORIES

The Accessories that are supplied with the device are:

A. SpineAssist Surgical Accessories Kit
B. SpineAssist Setup Kit
C. C-InSight Extremities Target Kit
D. C-InSight Spine Target Kit
E. Image Adaptor 9"/12"

All accessories are identical to the previously cleared SpineAssist and C-InSight accessories, and are described in the previously cleared 510(k) submissions. The TenZing application does not require any additional new accessories.

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1.5 STERILIZATION

The TenZing application does not have any dedicated accessories or disposable parts. TenZing application is a software product and does not include any sterilized parts. There are accessories and disposables which belong to the SpineAssist and the C-InSight. Those accessories and disposables are described in previously cleared 510(k) submissions.

1.6 TECHNICAL CHARACTERISTICS

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APPENDIX 2-1: FIGURES

Figure 3 - TenZing Workstation (Engineering Drawing)

Figure 4 – TenZing Flow Chart

Figure 5 - TenZing Application – Use of C-InSight Application with SpineAssist Device mounted

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(b)(4) SUMMARY OF SAFETY AND EFFECTIVENESS

(b)(4)

(b)(4)

(b)(4)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ¿ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

July 30, 2010

MAZOR SURGICAL TECHNOLOGIES LTD.
C/O A. STEIN REGULATORY AFFAIRS CONSULTING
20 HATA'AS ST.
KFAR SABA
ISRAEL 44425
ATTN: AHAVA STEIN

510k Number: K102130
Received: 7/29/2010
Product: TENZING SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

APPENDIX 5-4

List of Software Changes to SpineAssist and C-InSight System Software

M:\Mazor Robotics\
Spine Theater Special

SpineAssist Software Changes

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(b)(4)

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MAZOR
Surgical Technologies

System/Software Test Results (STR) for

C-Insight Version (b)(4)

Document information:

Project Name	C-Insight
Project Number	(b)(4)
Document No.	

Revision History:

Date	Revision Level	Author	ECO No.	Change Description
11.04.2010	(b)(4)	(b)(4)	(b)(4)	(b)(4)
25.1.2009	(b)(4)	(b)(4)	(b)(4)	

Approvals:

(b)(4)

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MAZOR
Surgical Technologies

System/Software Test Results (STR) for

TenZing Version (b)(4)

Document information:

Project Name	TenZing
Project Number	
Document No.	(b)(4)

Revision History:

Date	Revision Level	Author	ECO No.	Change Description
29.03.2010	(b)(4)	(b)(4)	(b)(4)	TenZing Ver (b)(4)

Approvals:

(b)(4)

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APPENDIX 5-2:

RISK ANALYSIS DOCUMENT

M:\Mazor Robotics\
Spine Theater Special

Imagine the Difference
Mazor
Surgical Technologies

Risk Analysis for TenZing System

Document information:

Project Name	TenZing System
Document No.	(b)(4)

Revision History:

Date	Revision Level	Author	ECO No.	Change Description
11.3.10	(b)(4)	(b)(4)	(b)(4)	version

Approvals:

(b)(4)

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Table of Contents

510(k) Review

K102130

Traditional____ **Abbreviated_____** **Special __X___**

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Fax: +972-9-768534
E-mail: ahava@asteinrac.com

Company Name: Mazor Surgical Technologies, Ltd.
Address: 7 HaEshel Str.
P.O.B. 3104
Southern Caesarea Industrial Park, 38900
Israel

510(k) Number: k102130

Trade Name: TenZing System

Dated: July 25, 2010
Received: July 29, 2010

Product Code: HAW **Class:** II **FR Classification No.:** 21 CFR 882.4560
LLZ II 21 CFR 892.2050

Manufacturing Address: 7 Ha'Eshel St.
Southern Caesarea Industrial Park, 38900
Israel

Common Name: Stereotactic spinal instrument / Radiological image processing software

(b)(5)

(b)(5)

(b)(5)

Kang, S. Andrew

From: Ahava [ahava@asteinrac.com]
Sent: Wednesday, August 25, 2010 7:48 AM
To: Kang, S. Andrew
Subject: RE: Special 510(k), TenZing System, k102130

Dear Andrew,

(b)(4)

Thanks,
Ahava

****
A. Stein - Regulatory Affairs Consulting Ltd.
Beit Hapaamon (Suite 102)
20 HaTaas Str. (P.O.B. 124)
Kfar Saba 44425 ISRAEL
Tel: +972-9-7670002
Fax: +972-9-7668534
E-mail: ahava@asteinrac.com
****

From: Kang, S. Andrew [mailto:S.Kang@fda.hhs.gov]
Sent: Monday, August 23, 2010 6:27 PM
To: 'Ahava'
Subject: RE: Special 510(k), TenZing System, k102130

Mr. Stein,

(b)(4)

Andrew Kang, MD
Reviewer
CDRH/OIVD/DRAD

From: Ahava [mailto:ahava@asteinrac.com]

Sent: Sunday, August 22, 2010 3:36 AM
To: Kang, S. Andrew
Subject: RE: Special 510(k), TenZing System, k102130

Dear Andrew,

(b)(4)

Thanks,
Ahava

****
A. Stein - Regulatory Affairs Consulting Ltd.
Beit Hapaamon (Suite 102)
20 HaTaas Str. (P.O.B. 124)
Kfar Saba 44425 ISRAEL
Tel: +972-9-7670002
Fax: +972-9-7668534
E-mail: ahava@asteinrac.com
****

From: Kang, S. Andrew [mailto:S.Kang@fda.hhs.gov]
Sent: Friday, August 20, 2010 12:08 AM
To: 'ahava@asteinrac.com'
Subject: Re: Special 510(k), TenZing System, k102130

Mr. Ahava Stein,

(b)(4)

Andrew Kang, MD
CDRH/OIVD/DRAD

[redacted] Information from ESET NOD32 Antivirus, version of virus signature database 5394 (20100824) [redacted]

The message was checked by ESET NOD32 Antivirus.

http://www.eset.com

 12

Kang, S. Andrew

From: Ahava [ahava@asteinrac.com]
Sent: Sunday, August 22, 2010 3:36 AM
To: Kang, S. Andrew
Subject: RE: Special 510(k), TenZing System, k102130
Attachments: (b)(4)

Dear Andrew,

(b)(4)

Thanks,
Ahava

****
A. Stein - Regulatory Affairs Consulting Ltd.
Beit Hapaamon (Suite 102)
20 HaTaas Str. (P.O.B. 124)
Kfar Saba 44425 ISRAEL
Tel: +972-9-7670002
Fax: +972-9-7668534
E-mail: ahava@asteinrac.com
****

From: Kang, S. Andrew [mailto:S.Kang@fda.hhs.gov]
Sent: Friday, August 20, 2010 12:08 AM
To: 'ahava@asteinrac.com'
Subject: Re: Special 510(k), TenZing System, k102130

(b)(4)

Andrew Kang, MD A. Kang
CDRH/OIVD/DRAD

Indications for Use

510(k) Number (if known): K102130

Device Name: TenZing System

Indications for Use:

The TenZing System is a combination of the SpineAssist System and C-InSight System, allowing the C-InSight application to run on the SpineAssist Workstation:

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.

The C-InSight software provides a processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image.
It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects, particularly for orthopedic applications.

Prescription Use __√_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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
E-mail (b)(6)

July 25, 2010

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
USA

Re: Special 510(k) – TenZing System: Device Modification for the SpineAssist Device (K073467)

Attention: Document Mail Clerk

Mazor Surgical Technologies Ltd., has requested that I represent them in the capacity of authorized regulatory agent for the purpose of obtaining FDA marketing clearance for the TenZing System. It is in that capacity that I am communicating with you. The TenZing System is a device modification of the SpineAssist System (K073467), designed to incorporate both the original SpineAssist System (manufactured by Mazor Surgical Technologies Ltd. and cleared under 510(k) No. K07346) and the C-InSight device (manufactured by Mazor Technologies Ltd. and cleared under 510(k) No. K081672) in one workstation.

Attached please find the Special Premarket Notification submission for the TenZing System. A table of contents for this 510(k) is presented following the cover letter.

Following is information required under 21 CFR 807.87 and suggested by FDA guidelines:

Type of 510(k) submission: Special

Device type: Combination of:

a. Spinal Stereotaxic Instrument; and

b. System, Image Processing, Radiological

510(k) Submitter:

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
E-mail: armin@mazorst.com

Official Correspondent:

Ahava Stein
A. Stein – Regulatory Affairs Consulting
20 Hata'as St.
Kfar Saba 44425
Israel
Tel. + 972-9-7670002
Fax. +972-9-7668534
E-mail: ahava@asteinrac.com

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This is to notify you of the intention of Mazor Surgical Technologies Ltd., to manufacture and market the following device:

Device trade or proprietary name: TenZing System

Common Name: Combination of:

a) Spinal Stereotaxic Instrument; and
b) 3-D Reconstruction Tool for Mobile X-Ray Devices

Classification and Product Code: The subject of this Special 510(k) is the TenZing System, with the CFR classification section:

a) For the SpineAssist - 882.4560; Stereotaxic Instrument with product code HAW.
b) For the C-InSight - 892.2050; System, Image Processing, Radiological and product code LLZ.

Device Class and Panel: Stereotaxic instruments are Class II devices. The classification panel is the Neurology Devices Panel. A Radiological Image Processing System is also a Class II device. The classification panel is the Radiology Panel.

Intended Use: Refer to 510(k) indications for use form.

Establishment Registration Number: 3005075696

514 Performance Standards: There are no mandatory performance standards under the Federal Food, Drug and Cosmetic Act, for this type of device.

Manufacturing Location:

Mazor Surgical Technologies Ltd.
7 HaEshel Str.
P.O.B. 3104
Southern Caesarea Industrial Park, 38900
ISRAEL

Reason for Submission: Device modifications - combination of two cleared devices from the same manufacturer.

Substantial Equivalence: The TenZing System is based on and is substantially equivalent to a combination of the following devices: SpineAssist System (manufactured by Mazor Surgical Technologies and the subject of 510(k) document no. K073467) and C-InSight System (also manufactured by Mazor Surgical Technologies and the subject of 510(k) document no. K081672)
A comparison table and detailed discussion are presented in Section 3 of this application.

Proposed Labeling: The user's instructions for the TenZing System are attached in Section 4 (Product Labeling). These instructions describe TenZing System procedures, its intended use and the directions for its use. A product brochure and package label is also included in the Product Labeling Section.

Confidentiality: Mazor Surgical Technologies Ltd, considers its intent to market the TenZing Spinal System in the USA as confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employees, others with a financial interest in the Company, its advertising or law firms, and its consultants. The Company, therefore, requests FDA not to disclose the existence of this application until such time as final action on the submission is taken. In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 CFR § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that FDA consult with the Company as provided in 21 CFR § 20.45 before making any part of this submission publicly available.

This document presents additional information and data that are intended to establish substantial equivalence and meet the requirements of a 510(k). This supportive information is divided into the following sections:

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1. Indications for use statement
2. Description of the modified device
3. Comparison to the cleared device
4. Product labeling
5. Summary of the design control activities, including Declaration of Conformity with Design Controls
6. Truthful and Accurate Statement
7. 510(k) Summary of Safety and Effectiveness

I trust that the information included in this application will be adequate to allow for its prompt review. If you have any questions or comments, please don't hesitate to contact me at the following telephone number: +972-9-767-0002 or fax number: +972-9-7668534 or e-mail address: ahava@asteinrac.com .

Sincerely Yours,

(b)(6)

Ahava Stein
A. Stein - Regulatory Affairs Consulting, for
Mazor Surgical Technologies Ltd.

APPENDIX 5-3

SOFTWARE TESTING

1 - SRS for TenZing Version (b)(4) M:\Mazor Robotics\ Spine Theater Special

2 - STP for TenZing Version (b)(4) M:\Mazor Robotics\ Spine Theater Special

3 - STD for TenZing Version (b)(4) M:\Mazor Robotics\ Spine Theater Special

4 - STR for TenZing Version (b)(4) M:\Mazor Robotics\ Spine Theater Special

5 - STD for SpineAssist Version (b)(4) M:\Mazor Robotics\ Spine Theater Special

6 - STR for SpineAssist Version (b)(4) M:\Mazor Robotics\ Spine Theater Special

7 - OTS Validation for SpineAssist (b)(4) M:\Mazor Robotics\ Spine Theater Special

8 - STD for C-InSight Version (b)(4) M:\Mazor Robotics\ Spine Theater Special

9 - STR for C-InSight Version (b)(4) M:\Mazor Robotics\ Spine Theater Special

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SECTION 3 – COMPARISON TO CLEARED DEVICE

The TenZing system is a device modification of the SpineAssist system, designed to incorporate both the original SpineAssist system (cleared under 510(k) No. K073467) and the C-InSight system (cleared under 510(k) No. K081672), both manufactured by Mazor Ltd., into one workstation.

The comparison of the modified combined system, with the original, unchanged systems (SpineAssist system cleared under 510(k) No. K073467 and the C-InSight system cleared under 510(k) No. K081672) is provided to demonstrate substantial equivalence regarding the intended use of the system and the basic technological characteristics of the application.

A comparison table is provided in the following pages, comparing the intended use and technological characteristics of the modified TenZing system to the predicate SpineAssist and C-InSight systems.

A discussion of the similarities and differences between the modified TenZing system to the SpineAssist system cleared under K073467 and the C-InSight system cleared under K081672 is found following the comparison table.

COMPARISON TABLE:

Intended Use and Technological Characteristics	**TENZING SYSTEM**	**SPINE ASSIST SYSTEM CLEARED UNDER K073467**	**C-INSIGHT SYSTEM CLEARED UNDER K081672**
Product Code / Class	HAW/ Class II	HAW/ Class II	LLZ/ Class II
Intended Use	For precise positioning of surgical instruments or implants during general spinal surgery. The SpineAssist system may be used in either open or percutaneous procedures. Provides processing and conversion of 2D fluoroscopic projections from standard C-arms into volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects particularly for orthopedic applications.	For precise positioning of surgical instruments or implants during general spinal surgery. The SpineAssist system may be used in either open or percutaneous procedures.	Provides processing and conversion of 2D fluoroscopic projections from standard C-arms into volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects particularly for orthopedic applications.
System major modules	SpineAssist including C-InSight application	SpineAssist	C-InSight
System components	Workstation SpineAssist accessories SpineAssist device C-InSight accessories	Workstation SpineAssist accessories SpineAssist device	Workstation C-InSight accessories
Dimensions	1.96 x .77 x .55m (77 x 30 x 22in)	1.96 x .77 x .55m (77 x 30 x 22in)	91.6 x 49.7 x 77.6 cm
Weight	125 Kg	125 Kg	30 Kg
Power Requirements	110-120 VAC / 60 Hz 220-240 VAC / 50 Hz	110-120 VAC / 60 Hz 220-240 VAC / 50 Hz	110-120 VAC / 60 Hz 220-240 VAC / 50 Hz
Patient Contact Materials	Same as SpineAssist and C-InSight	Biocompatible	Biocompatible

DISCUSSION OF SIMILARITIES AND DIFFERENCES:

INTENDED USE:

The TenZing system is a device modification of the SpineAssist system, designed to incorporate both the original SpineAssist system (cleared under 510(k) No. K073467) and the C-InSight system (cleared under 510(k) No. K081672), both manufactured by Mazor Ltd., into one workstation. As such, the TenZing system is substantially equivalent to both the original SpineAssist system and the C-InSight system. 510(k) Summaries of both the predicate devices are provided in Appendix 3-1.

The TenZing system is intended for the combined intended uses of the SpineAssist system and the C-InSight system. The SpineAssist is intended for use for precise positioning of surgical instruments or implants during general spinal surgery. The SpineAssist system may be used in either open or percutaneous procedures. The C-InSight is intended for use to provide processing and conversion of 2D fluoroscopic projections from standard C-arms into volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects particularly for orthopedic applications.

The TenZing system, combining both predicate device SW applications, is intended (when activating the SpineAssist application) for use for precise positioning of surgical instruments or implants during general spinal surgery. It may be used in either open or percutaneous procedures. The TenZing system is also intended for use (when activating the C-InSight application) to provide processing and conversion of 2D fluoroscopic projections from standard C-arms into volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects particularly for orthopedic applications.

Thus, the intended use of the modified device is substantially equivalent to that of the combination of the predicate devices.

TECHNOLOGICAL CHARACTERISTICS:

The TenZing system has the same basic technological characteristics as the predicate devices, i.e., the SpineAssist and the C-InSight systems. The original devices were not changed, except for the modifications required for operating both software programs from the same workstation. The modified TenZing system has the same device components consisting of a workstation, software applications, user interface and display. The modified device uses the same mechanism of action, with no change. The TenZing console is identical to the original SpineAssist console. The original devices were not modified, except for the software changes needed to allow simultaneous operation from a single workstation. The software changes were validated and are described in more detail in Section 4 – Summary of Design Control Activities.

The specifications of the modified device are also identical to the specifications of the predicate devices, as the software applications were not changed.

SUMMARY

The intended use and technological characteristics of the modified system are substantially equivalent to the intended use and technological characteristics of the combination of predicate SpineAssist and C-InSight systems. The SpineAssist system specifications within the TenZing system are identical to the specifications of the original SpineAssist system and the C-InSight system specifications within the TenZing system are identical to the specifications of the original C-InSight system. The minor differences in system design do not raise new safety or effectiveness concerns.

Due to the changes performed in the software (to allow operation of both software programs from the same console), the modified device was subjected to the following tests:

- Software Testing according to FDA Guidelines

The software test results show that the changes made to the modified system do not raise new safety or effectiveness concerns.

Consequently, it can be concluded that the modified SpineAssist system, i.e., the TenZing system, is substantially equivalent to a combination of the SpineAssist system cleared under K073467 and the C-InSight system cleared under K081672, and therefore, may be legally marketed in the USA.

APPENDIX 3-1

Predicate Device 510(k) Summaries:

1. **510(k) Premarket Notification Summaries for the SpineAssist System (K073467)**
2. **510(k) Premarket Notification Summary for the C-InSight (K081672)**

510(k) Premarket Notification Summaries for the SpineAssist System (K073467)

M:\Mazor Robotics\
Spine Theater Special

M:\Mazor Robotics\
Spine Theater Special

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Skip to Section Content Menu Skip to Common Links

510(k) Premarket Notification

510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA

New Search Back To Search Results

Device Classification Name	Neurological Stereotaxic Instrument
510(K) Number	K073467
Device Name	SPINEASSIST SYSTEM
Applicant	MAZOR SURGICAL TECHNOLOGIES LTD. 20 Hata'as St. Kfar Saba,
Contact	Ahava Stein
Regulation Number	882.4560
Classification Product Code	HAW
Date Received	12/10/2007
Decision Date	05/23/2008
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Neurology
Review Advisory Committee	Neurology
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

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

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)

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

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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

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 __√__ (Per 21 C.F.R. 801 Subpart D) OR Over-The-Counter Use___ (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

510(k) Premarket Notification Summary for the C-InSight (K081672)

M:\Mazor Robotics\
Spine Theater Specia

M:\Mazor Robotics\
Spine Theater Special

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510(k) Premarket Notification

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CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA

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Device Classification Name	System, Image Processing, Radiological
510(K) Number	K081672
Device Name	C-INSIGHT
Applicant	MAZOR SURGICAL TECHNOLOGIES LTD. 20 Hata'as St. Kfar Saba,
Contact	Ahava Stein
Regulation Number	892.2050
Classification Product Code	LLZ
Date Received	06/13/2008
Decision Date	08/15/2008
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Radiology
Review Advisory Committee	Radiology
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

K081672

AUG 15 2008

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

DISCASSIST™ SYSTEM

510(k) Number K_____

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:	ahava@asteinrac.com

Name of the device:

C-InSight System

Trade or proprietary name, if applicable:

C-InSight System

Common or usual name:

3-D Reconstruction Tool for Mobile X-ray Devices.

52

Establishment Registration No.:

3005075696

Classification Name:

System, Image Processing, Radiological

Classification:

FDA has classified Radiological Image Processing systems as a Class II medical device, with product code LLZ and 21 CFR classification code 892.2050. Review by the Radiology Panel.

Predicate Device:

The C-InSight™ system is substantially equivalent to the Siremobil Iso-C 3D software (manufactured by Siemens Medical Systems, Inc. and subject of 510(k) document no. K003266, K032280, K040347) and O-Arm Imaging System software (manufactured by Breakaway Imaging and subject of 510(k) document no. K050996 and K060344).
A comparison table and detailed discussion are presented in Section 12 of this application.

Device Description:

C-InSight is a software based product, which converts a sequence of Two-dimensional fluoroscopy images into a 3D volume, intraoperatively. The C-InSight is an add-on to commercially available mobile x-ray systems.
Two-dimensional imaging is available nowadays in every operating room in the form of a mobile C-Arm. However, there is often a need for a three-dimensional imaging

during the operation especially due to the rise in the scope of minimally invasive procedures.

To answer the need for a reasonably priced, easy to use and highly mobile intra-operative 3D imaging, the C-InSight was developed.

C-InSight is a software-based product, which gives the solution for 3D imaging intra-operatively, using a standard 2D Mobile C-Arm.

Coupling the 3D capabilities of the C-InSight using existing C-Arms in the operating rooms, can give surgeons a real-time assessment of implant placement.

The clinician who uses the C-InSight should identify the anatomical area which is scanned, and cover it with the C-InSight Reference Belt. The user scans the body and the C-InSight Reference Belt for 20 seconds. The scanned data is sent to the C-InSight processing unit, which converts this data into three-dimensional volume.

The clinician is then able to view the scanned data in different anatomical projections: AP, LT, AX and 3D volume.

The main components of the C-Insight system include:

A. Workstation
B. Accessories, including C-InSight Reference Belt and Image Adaptor
C. Disposable kit, including C-InSight Sterile Sheath

Intended Use / Indication for Use:

The C-InSight software provides a processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image.

It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects particularly for orthopedic applications.

Comparison of Technological Characteristics with the predicate device:

The C-InSight system is similar to the predicate device regarding intended use and regarding technological characteristics. All are intended to be used when the clinician and patient benefit from generated 3D imaging of high contrast objects. They all include software which provides conversion of 2D fluoroscopic projections from C-Arms into a volumetric 3D image. The C-InSight system uses a reference belt and target recognition algorithms to calculate the relative projection and location coordinates of each image, while the predicate devices use built-in sensors to receive these coordinates.

Non-Clinical Performance Data

The following performance tests were conducted on the C-InSight system:

1. Software Validation (IEC 60601-1-4 & FDA Guidelines)
2. C-InSight synthetic accuracy test.
3. C-InSight spine accuracy test.
4. C-InSight accuracy vs. CT (cadaver tests)
5. Image Quality test
6. Radiation Dose Exposure test

Clinical Performance Data

Not Applicable

Conclusions Drawn from Non-Clinical and Clinical Tests:

The performance tests demonstrate that C-InSight system may be safely and effectively used in surgical operation rooms, as an 3D visualization software, particularly for orthopedic applications. The software validation and accuracy performance tests demonstrate that the C-InSight system meets its design and performance specifications and is substantially equivalent to the previously cleared systems.

Substantial Equivalence:

In summary, the intended use of the C-Insight system is substantially equivalent to a combination of the Siremobil Iso-C 3D system and the O-Arm Imaging System. Furthermore, the basic technological characteristics of the C-InSight system are identical to the predicate devices. The differences in the technological characteristics do not raise new questions of safety and effectiveness. Consequently, the C-InSight system is substantially equivalent to the Siremobil Iso-C 3D system and the O-Arm Imaging System device.

Performance Standards:

The C-InSight™ system complies with the voluntary recognized standards:

1. Software Validation (IEC 60601-1-4 & FDA Guidelines)
2. Medical Electrical Equipment (IEC 60601-1 / 2)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2008

Mazor Surgical Technologies Ltd.
% Ms. Ahava Stein/ Ofer Hornick
Consultant
A. Stein – Regulatory Affairs Consulting
20 Hata'as St., Kfar Saba, 44425
ISRAEL

Re: K081672
Trade/Device Name: C-Insight System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 11, 2008
Received: June 13, 2008

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.

C7

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 one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

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,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):_____

Device Name: C-InSight System

Intended Use Statement:

The C-InSight software provides a processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image.
It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects particularly for orthopedic applications

Prescription Use __√__ (Per 21 C.F.R. 801 Subpart D)

OR

Over-The-Counter Use___ (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 Reproductive, Abdominal and Radiological Devices
510(k) Number K081672

K102130

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

FDA CDRH DMC

JUL 29 2010

Received

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

MAZOR SURGICAL TECHNOLOGIES LTD
7 Ha'Eshel St
P.O.Box 3104
Caesarea Industrial Park, South
Caesarea 38900
IL

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
Ahava Stein

2.1 E-MAIL ADDRESS
(b)(6)

2.2 TELEPHONE NUMBER (include Area code)
97297670002

2.3 FACSIMILE (FAX) NUMBER (include Area code)
97297668534

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD108211

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) 25-Jul-2010

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

K-34
NE
II 17

MAZOR
Surgical Technologies

System/Software Test Plan (STP) for

TenZing Version (b)(4)

Document information:

Project Name	TenZing
Project Number	(b)(4)
Document No.	

Revision History:

Date	Revision Level	Author	ECO No.	Change Description
08.03.2010	(b)(4)	(b)(4)	(b)(4)	

Approvals:

	Title	Name	Date	Signature
(b)(4)				

(b)(4)

(b)(4)

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510(k) Review

K102130

Traditional____ **Abbreviated**_____ **Special** __X__

Contact: Ahava Stein
A. Stein- Regulatory Affairs Consulting
20 Hata'as St.
Kfar Saba 44425
Israel
Tel: +972-9-7670002
Fax: +972-9-768534
E-mail: ahava@asteinrac.com

Company Name: Mazor Surgical Technologies, Ltd.
Address: 7 HaEshel Str.
P.O.B. 3104
Southern Caesarea Industrial Park, 38900
Israel

510(k) Number: k102130

Trade Name: TenZing System

Dated: July 25, 2010
Received: July 29, 2010

Product Code: HAW **Class:** II **FR Classification No.:** 21 CFR 882.4560
LLZ II 21 CFR 892.2050

Manufacturing Address: 7 Ha'Eshel St.
Southern Caesarea Industrial Park, 38900
Israel

Common Name: Stereotactic spinal instrument / Radiological image processing software

(b)(5)

(b)(5)

Applicable Guidance(s): 510(k) Paradigm

SPECIAL 510(k): Device Modification
ODE Review Memorandum

To: THE FILE RE: DOCUMENT NUMBER K102130

(b)(5)

Andrew Kang, MD
(Reviewer's Signature)

8/25/10
(Date)

Comments (b)(5)

sak 510(k) (449)

MAZOR
Surgical Technologies

System Requirements Specification
(SRS) for

TenZing Version (b)(4)

Document information:

Project Name	TenZing
Document No.	(b)(4)

Revision History:

Date	Revision Level	Author	ECO No.	Change Description
10.3.10	(b)(4)	(b)(4)	(b)(4)	

Approvals:

(b)(4)

(b)(4)

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K102130

Indications for Use

510(k) Number (if known): K102130

Device Name: TenZing System

Indications for Use:

The TenZing System is a combination of the SpineAssist System and C-InSight System, allowing the C-InSight application to run on the SpineAssist Workstation:

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.

The C-InSight software provides a processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image.
It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects, particularly for orthopedic applications.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K102130

MAZOR
Surgical Technologies

System/Software Test Description (STD) for

C-Insight Version (b)(4)

Document information:

Project Name	C-Insight
Project Number	(b)(4)
Document No.	

Revision History:

Date	Revision Level	Author	ECO No.	Change Description
11.04.2010	(b)(4)			
15.09.2009				
12.2008				

Approvals:

(b)(4)

CONFIDENTIAL for internal use only

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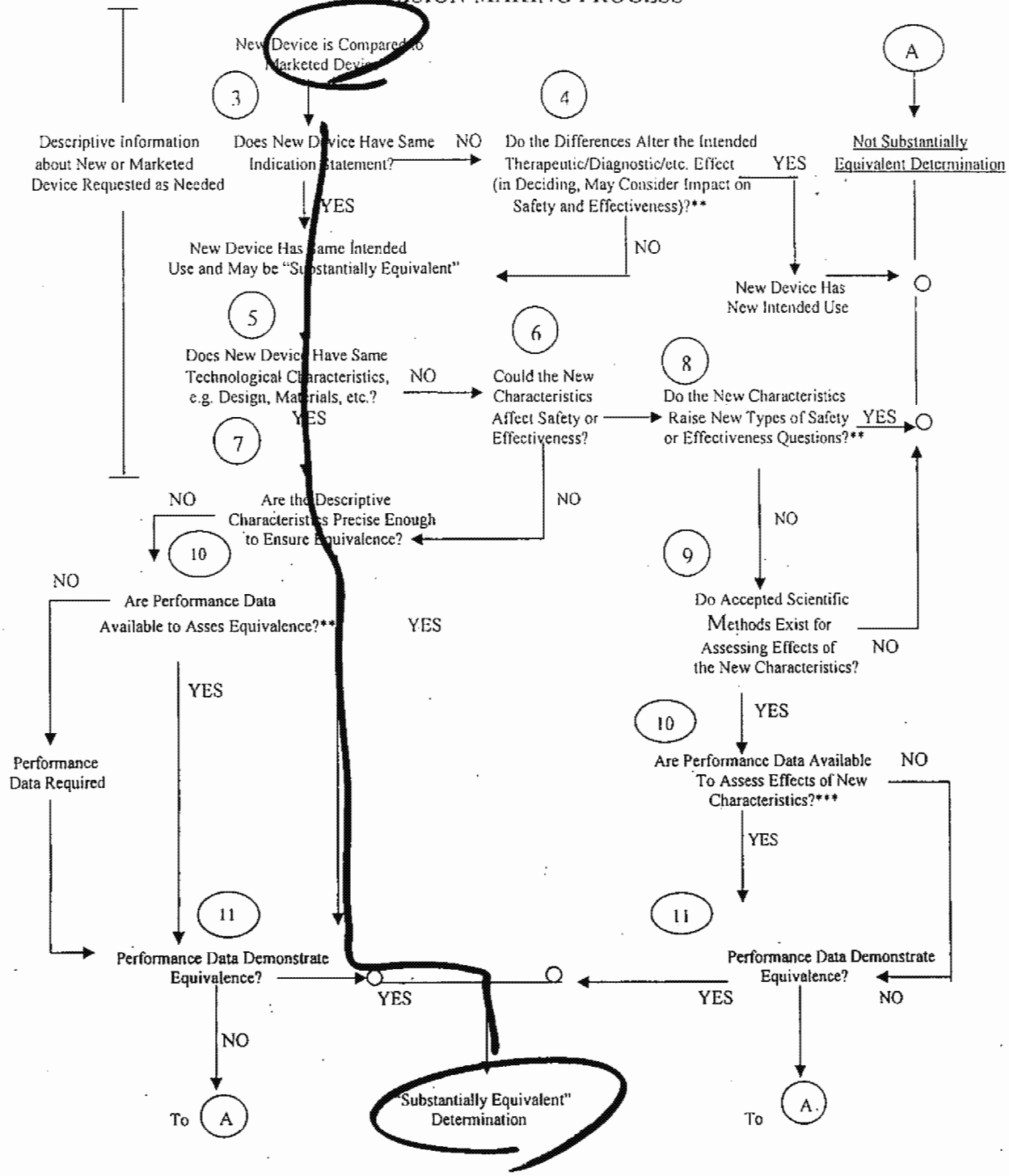
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

APPENDIX 5-5

1. FDA Forms 3654

M:\Mazor Robotics\
Spine Theater Special

IEC 60601-1

M:\Mazor Robotics\
Spine Theater Special

IEC 60601-1-2

2. Test Certificates

M:\Mazor Robotics\
Spine Theater Special

IEC 60601-1

M:\Mazor Robotics\
Spine Theater Special

IEC 60601-1-2

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1 Medical electrical equipment - part 1: general requirements for safety 1: collateral standard: safety requirements for medical electrical systems (1988 + A1: 1991 + A2: 1995)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 5-4	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1 MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR SAFETY 1: COLLATERAL STANDARD: SAFETY REQUIREMENTS FOR MEDICAL ELECTRICAL SYSTEMS (1988 + A1: 1991 + A2: 1995)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
NA

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2:Medical Electrical Equipment, Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests (+A1:2004)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 5-34	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
s this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

PSC Graphics: (301)-443-1090

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

S[illegible]NDARD TITLE
IEC 60601-1-2:MEDICAL ELECTRICAL EQUIPMENT, PART 1-2: COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY – REQUIREMENTS AND TESTS (+A1:2004)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
NA

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

S[illegible]TION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

(b)(4)

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SECTION 5 – SUMMARY OF DESIGN CONTROL ACTIVITIES

Following is a summary of the design control activities carried out during the development of the TenZing system, according to the FDA Quality System Requirements. The company's declaration of conformity with the design control activities is attached in Appendix 5-1.

RISK ANALYSIS

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MAZOR
Surgical Technologies

System/Software Test Description (STD) for

SpineAssist Version (b)(4)

Document information:

Project Name	SpineAssist
Project Number	(b)(4)
Document No.	

Revision History:

Date	Revision Level	Author	ECO No.	Change Description
25.1.2010	(b)(4)	(b)(4)	(b)(4)	
19.08.2009	(b)(4)	(b)(4)		

Approvals:

(b)(4)

(b)(4)

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name S. Kang

Subject: 510(k) Number K102130

To: The Record

Please list CTS decision code SE

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- ☐ Hold (Additional Information or Telephone Hold).
- ☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			✓
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓ ✓ ✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number	Class*	Product Code
21 CFR 882.4560		HAW

(*If unclassified, see 510(k) Staff)

Additional Product Codes: LLZ

Review: _____
(Branch Chief) (Branch Code) (Date)

Final Review: _____ 8/26/10
Acting (Division Director) (Date)

MAZOR Surgical Technologies

Off The Shelf (OTS)

Software Validation Report

For SpineAssist V(b)(4)

Document information:

Project Name	SpineAssist
Document No.	(b)(4)

Revision History:

Date	Revision Level	Author	ECO #	Change Description
02.03.2010	(b)(4)	(b)(4)	(b)(4)	
01.11.09	(b)(4)	(b)(4)		

Approvals:

(b)(4)

(b)(4)

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MAZOR
Surgical Technologies

System/Software Test Description (STD) for

TenZing Version (b)(4)

Document information:

Project Name	TenZing
Project Number	(b)(4)
Document No.	

Revision History:

Date	Revision Level	Author	ECO No.	Change Description
22.3.2010	(b)(4)	(b)(4)		TenZing Ve(b)(4)

Approvals:

(b)(4)

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