K123023

FEB 8 2013

510(k) SUMMARY
(Modified February 4, 2013)

SURGICAL THEATER
SURGERY REHEARSAL PLATFORM

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Surgical Theater, LLC
151 Innovation Drive
Elyria, Ohio 44035

Contact Person:

Mordechai Avisar
CEO/President
Surgical Theater, LLC
Date Prepared: January 26, 2013

Name of Device and Name/Address of Sponsor

Device Name: Surgery Rehearsal Platform
Regulation Name: Picture archiving and communications system
Regulation Number: 892.2050
Product Code: LLZ

Sponsor:

Surgical Theater, LLC
151 Innovation Drive
Elyria, Ohio 44035

Predicate Device

Simbionix PROcedure Rehearsal Studio (K112387)

Intended Use

The Surgical Theater, LLC Surgery Rehearsal Platform is intended for use as a software interface and image segmentation system for the transfer of imaging information from CT or MR medical scanner to an output file. It is also intended as pre-operative software for simulating/evaluation surgical treatment options.

Technological Characteristics and Substantial Equivalence

A. Device Description

The Surgery Rehearsal Platform (SRP) is software based medical image management system. It is intended for use as a software interface and image segmentation system, for the transfer of imaging information from a CT or MR medical scanner, to an output file. It is also intended as pre-operative software for simulation and evaluation of surgical treatment options.

The SRP software has the capability of creating 3D models of patient data from 2D scan slices. Additionally, it provides the user with ability to input, display, color, and manipulate the 2D scan slices via a 3D representation.

B. Substantial Equivalence

The Surgical Theater, LLC Surgery Rehearsal Platform is substantially equivalent to the Simbionix PROcedure Rehearsal Studio (K112387)

Performance Data

The Surgery Rehearsal Platform has been successfully tested, verified and validated to ensure that it meet specifications.

Testing Summary:

Test Plans were written and executed internally which confirmed that the SRP meets specified requirements. Specified requirements include equivalent features and technical characteristics as the predicate device. The test results confirmed that SRP is substantially equivalent to the predicate. The submission includes the comprehensive system test plans, the pass/fail criteria and results.

Functional verification testing was conducted to verify that design outputs met design input requirements. The verification effort focused on verifying that design inputs described in system and software requirements specification documents are traceable to design outputs including component specifications, BOMs, and software design documents. Verification activities were performed by Quality personnel.

Functional validation testing was conducted to ensure that the SRP meets user needs and intended use. Validation was performed using SRP system and complete production version software. Testing was performed by Quality personnel on each supported system configuration (e.g. 2D vs. 3D Stereoscopic) using documented software test procedures.

In addition to the functional validation of the SRP system software, the system was validated by surgeons to ensure the system meets end-user requirements. This validation

consisted of both qualitative and quantitative assessments, and confirmed that the SRP meets user needs and intended use.

Risk analysis was performed in accordance with ISO 14971 (2007) standard for risk analysis. A risk management file verification and validation was conducted which included a desk audit and, where applicable, system testing. System testing included any mitigation detailed in software test procedures for individual applications.

Comparison of Technological Characteristics

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS		
Characteristic	**Simbionix PROcedure**	**Surgery Rehearsal Platform**
510(k) Accession Number	K112387	123023
Clearance Date	12/27/2011	TBD
Computer	PC Workstation	Same
Image Sources	CT and MRI	Same
Indications for Use	Software interface and image segmentation system for the transfer of imaging information from CT or MR medical scanner to an output file. Pre-operative software for simulating/evaluation surgical treatment options.	Same
Data Transfer Method	CD or USB	Same
Preoperative Planning	Yes	Yes
Patient Contact	No	No
Human Intervention for Interpretation of Images	Yes	Yes
Capability of creating 3D models of patient data from 2D scan slices.	Yes	Yes
Provides the user with ability to input, display, color, and manipulate the 2D scan slices via a 3D representation.	Yes	Yes
Image tools such as rotation, scaling and coloring.	Yes	Yes

Conclusions:

The Surgery Rehearsal Platform is substantially equivalent to and is as safe and effective as its predicate device. They have the same indications for use, are constructed from the same basic materials and both incorporate the same operational principles. Results of performance tests conducted on the Surgery Rehearsal Platform clearly demonstrate that the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 8, 2013

Surgical Theater, LLC
C/O Mordechai Avisar
CEO, President and Co-Founder
151 Innovation Drive
ELYRIA OH 44035

Re: K123023
Trade/Device Name: Surgical Rehearsal Platform
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: II
Product Code: LLZ
Dated: September 28, 2012
Received: December 20, 2012

Dear Mr. Avisar:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Surgery Rehearsal Platform

Indications for Use:

Surgery Theater, LLC Surgery Rehearsal Platform is intended for use as a software interface and image segmentation system for the transfer of imaging information from CT or MR medical scanner to an output file. It is also intended as pre-operative software for simulating/evaluating surgical treatment options.

Prescription Use __X___ 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* Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123023