510(K) SUMMARY

[as required by section 807.92(c)]

PROcedure Rehearsal Studio™

510(k) Number K 093269

AUG 2 0 2010

Applicant's Name:

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Contact Person:

Name: Shoshana (Shosh) Friedman
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Trade Name:

PROcedure Rehearsal Studio™

Classification Name:	System, Image Processing, Radiological
Regulation Number:	892.2050
Product Code:	LLZ
Classification:	Class II
Review Panel:	Radiology

Predicate Devices:

- Mimics® by Materiallise N.V., K073468.
- CardioCT by Shina System Ltd., K070226

Device Description:

The Simbionix PROcedure Rehearsal Studio software allows clinicians to create a patient specific 3D anatomical model based on a patient's CT for the purpose of simulating, analyzing and evaluating for preoperative surgical treatment options.

Once the 3D segmentation model has been exported to the Simbionix ANGIO Mentor Simulator Practice Environment, the physician can use it to create a library of modules for training and post-operative debriefing..

Intended Use:

The PROcedure Rehearsal Studio software is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner to an output file. It is also intended as pre-operative software for simulating/evaluating surgical treatment options.

Performance Data:

The device performance was validated through bench tests and phantom studies in comparison to the Mimics predicate device and was found substantially equivalent.

Conclusion:

Simbionix Ltd. believes that, based on the information provided in this submission, the PROcedure Rehearsal Studio™ is substantially equivalent to its predicate devices without raising any new safety and/or effectiveness issue.

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

Simbionix Ltd.
% Ms. Shoshana Friedman
President & CEO
Push-Med LLC
1914 J N Pease Pl.
CHARLOTTE NC 28262

AUG 2 0 2010

Re: K093269
Trade/Device Name: PROcedure Rehearsal Studio™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 21, 2010
Received: June 23, 2010

Dear Ms. Feiedman:

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K093269

Device Name:

Indications for Use:

The PROcedure Rehearsal Studio software is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner to an output file. It is also intended as pre-operative software for simulating/evaluating surgical treatment options.

Prescription Use __X___ (Per 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ ODUD

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

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