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7 510(k) Summary for the Soma Access Systems ExactTrack™ I Procedure Kit

The 510(k) Summary is provided on the following pages.

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510(k) Summary

Soma Access Systems ExactTrack™ I Procedure Kit

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R § 807.92.
Applicant	Soma Access Systems LLC
Submitter	Soma Access Systems LLC. 109 Laurens Road, Suite 4C Greenville, SC 29607 Tel: 612-990-0631 Fax: 651-209-0556
Contact Person	Genoa Atwood, Director of Quality
Date Prepared	August 30, 2011
Device Trade Name	Soma Access Systems ExactTrack™ I Procedure Kit
Device Common Name	Ultrasonic pulsed echo imaging system
Classification Name	EMT Device, Product Code IYO
Classification Panel	Radiology
Predicate Devices	eTRAX Needle System, eTRAX Variable Angle Needle Guidance System, Virtutrax Universal Tracker (K092619).
Intended use	The device is intended to provide physicians with tools for electromagnetic tracking of instruments with respect to image data.
Device Description	The Soma Access Systems ExactTrack™ I Procedure Kit consists of five disposable, sterile components: (1) needle/hub/magnet and needle protective sheath assembly, (2) cable sleeve, (3) elastic bands, (4) top shield assembly, and (5) bottom shield assembly. The needle/hub/magnet assembly consists of the needle, hub, magnet, and needle protective sheath. The needle is 18 gauge stainless steel and accepts a standard guidewire; the hub is an industry standard configuration modified to retain the magnet which is detected by OEM equipment electromagnetic sensors; the needle sheath protects the needle/hub/magnet during packaging and transportation. The cable sleeve is attached at one end to the assembled top and bottom shield by an elastic band and extends over the ultrasound transducer cable to prevent the transducer cable from coming in direct contact with the sterile field. The top and bottom shields' configuration has been designed to snap together while fitting

	tightly over OEM transducers. The top and bottom shields utilize a needle guide and needle lock during ultrasound procedures.
Performance data	Bench testing was performed to support a determination of substantial equivalence and consisted of comparative, biocompatibility, sterilization, and design verification. Results from this testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. A risk analysis for the proposed device was performed, and testing was conducted to validate the systems overall operations.
Summary of Substantial Equivalence	The Soma Access Systems ExactTrack™ I Procedure Kit utilizes substantially equivalent performance attributes and safety components as the predicate device. It shares the following similarities to the predicate devices: • Needle Guide • Sterile Sheath Covering of transducer/transducer cable • Needle Handle Assembly • Needle technology • Packaging • Principle of Operation
Conclusion	Based on the identical indications for use, technological characteristics and performance testing, Soma Access Systems LLC believes the Soma Access Systems ExactTrack™ I Procedure Kit is substantially equivalent to the eTRAX Needle System, eTRAX Variable Angle Needle Guidance System, Virtutrax Universal Tracker (K092619).

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

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SOMA Access Systems LLC
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K113680
Trade/Device Name: Soma Access Systems ExactTrack™ I Procedure Kit
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO & ITX
Dated: December 14, 2011
Received: December 15, 2011

Dear Mr. Job:

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,

Mary S Pastel

Mary S. Pastel, Sc.D.
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): _____

Device Name: Soma Access Systems ExactTrack™ I Procedure Kit

Indications for Use:

The Soma Access Systems ExactTrack™ I Procedure Kit is intended to provide physicians with tools for electromagnetic tracking of instruments with respect to image data.

Prescription Use X (Part 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 In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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