K092619

NOV 13 2009

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k):	CIVCO Medical 102 First Street South Kalona, IA 52247-9589 USA Phone: 319-656-4447 Fax: 877-218-0324
Contact Person:	Jim Leong
Date of Summary:	September 22, 2009
Trade/Proprietary Name:	Electromagnetic System
Classification Name:	EMT Devices
Product Code:	IYO JAK

Intended Use:
The device is intended to provide physicians with tools for electromagnetic tracking of instruments with respect to image data.

Device Description:
Electromagnetic tracking tool kit works in conjunction with images gathered by OEM imaging devices to provide physicians with a tool for image registration and/or tracking of instruments. This is accomplished by utilizing attachment brackets, needle guides, adhesive skin markers or fiducial markers, needles and other housings that are specially configured to contain an electromagnetic sensor

The electromagnetic sensor in the tracked instrument is used within an EM field introduced by OEM equipment. The position and orientation can be thus detected and combined with the acquired imaging to assist with navigating a tracked instrument.

The system also utilizes accessories in conjunction with the system to allow the users additional options for protecting the equipment from contamination, needle guidance, and image registration.

EMT Sensor Covers:
The cover allows use of a sensor for body surface, endocavity and intra-operative applications while helping to prevent transfer of microorganisms, body fluids and particulate material to the patient and healthcare worker.

EMT Slot Guide:
The disposable needle guide is intended to attach to a bracket and provide physicians with a tool to keep an instrument in plane during ultrasound procedures.

Skin Markers:
The skin markers are intended to provide an image registration point for use in fusion of sequential imaging data and intracorporeal instrument tracking when combined with appropriate software delivered in the OEM equipment.

Predicate Devices:

The following predicate devices were referenced in the submission.

K082185 – GE Medical Systems, GE Logiq E9 Diagnostic Ultrasound System
K080624 – CAS Innovation AG, NavStation / RAD EMT
K040050 – InstaTrack with Multiple Dataset Navigation
K053610 – ABARIS Computer assisted, image-guided surgery system
K970513 – Poly ultrasound probe cover
K974432, K011418, K002258 – UltraGuide
K882383 – Maggi ultrasound needle guide
K071204 – SiteRite 6 Ultrasound System and guide
K030064 – iLook 25 Needle Guide attachment and Bracket Assembly

Substantial Equivalence:

CIVCO Medical Instruments claims the proposed devices to be substantially equivalent to the devices previously cleared by FDA in the listings above. CIVCO Medical Instruments claims this equivalence because the proposed devices have equivalent intended uses, manufacturing materials, operating principals, and physical, operational specifications as compared to the predicate devices.

There are no significant differences between the proposed and predicate devices except that they have now been qualified with the GE Logiq E9 system.

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

CIVCO Medical Instruments Co., Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 53313

NOV 13 2009

Re: K092619
Trade/Device Name: Electromagnetic Tracking System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO
Dated: September 29, 2009
Received: September 30, 2009

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 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,

Janine M. Morris
Acting 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): K092619

Device Name: Electromagnetic Tracking System

Indications for Use:

The device is intended to provide physicians with tools for electromagnetic tracking of instruments with respect to image data.

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 Device Evaluation (ODE)

...vision Sign-Off)
...ision of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092619