K093713

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

JAN 19 2010

Regulatory Correspondent:

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Submitter of 510(k):

Civco Medical Instruments
102 First Street South
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James Leong
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Date of Summary: 12/21/2009

Trade/Proprietary Name: Ultrasound General Purpose Guidance System

Classification Name: Diagnostic Ultrasound Transducers

Product Code: ITX

Intended Use:

The guidance system is intended for directing instruments such as catheters, electrodes and needles into a targeted anatomical location of a patient relative to the imaging instrument for percutaneous procedures. Prior to use healthcare workers should be trained in ultrasonography. The following models are included in this submission:

MODEL	INTENDED USE
Ultra-Pro II™ Needle Guides	The bracket and disposable guide provide physicians with a tool for performing needle-guided (or catheter) procedures with the use of diagnostic ultrasound transducers.
Ultra-Pro 3™ Needle Guides	
AccuSITE Transverse Needle Guides	
Infiniti™ Needle Guides	
Multi-Pro 2000™ Needle Guides	
MAGGI II Plus™ Needle Guides	

Device Description:

The bracket and disposable guide provide physicians with a tool for performing needle-guided (or catheter) procedures with the use of diagnostic ultrasound transducers. The guide facilitates directing the device to a target to improve accuracy and repeatability.

Predicate Device:

K882383 - MAGGI SERIES ULTRA. NEEDLE, BIOPSY/CATHETER GUIDES

K071204 - SITE-RITE 6 ULTRASOUND SYSTEM, MODEL SITE-RITE 6

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 K882383, K071204 and K030064. CIVCO claims this equivalence because the proposed devices have an equivalent intended use, manufacturing materials, operating principles and physical operational specifications as compared to the predicate devices. The similarities and differences between the proposed and predicate devices have been identified and explained in the comparison matrix which has been included in Section 8 of this submission. These differences have no effect on safety and effectiveness

Performance Testing:

Verification was performed to ensure that device meets specified tolerances and works in conjunction with specifically designed adapter clip area. All of the appropriate performance testing can be found in Section 12 of this submission.

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

JAN 19 2010

Re: K093713
Trade/Device Name: Ultrasound General Purpose Guidance Systems
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Regulatory Class: II
Product Code: ITX
Dated: January 4, 2010
Received: January 5, 2010

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,

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

510(k) Number (if known):

Device Name: Ultrasound General Purpose Guidance System

Indications for Use:

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MAGGI II Plus™ Needle Guides	

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

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

(Division Sign-Off)
Division of Radiological Devices

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

510(k) Number K093713