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K030064

510(k) SUMMARY

iLook™ 25 Needle Guide Attachment and Bracket Assembly

SonoSite, Inc.
21919 30th Drive SE
Bothell, WA 98021-3904

Corresponding Official:
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Date of Summary: December 16, 2002

Device Name:

iLook™ 25 Needle Guide Attachment and Bracket Assembly

Common Name:

Diagnostic Ultrasound Transducer Accessory

Classification:

Device Class:	II
Classification Panel:	Radiology
C.F.R. Section:	892.1570
Product Code:	ITX

Legally Marketed Predicate Device:

The predicate devices that SonoSite, Inc. is claiming substantial equivalence to are:

a) Site-Rite Disposable Needle Guides with Bracket Integral to Transducer, and;
b) CIVCO Sterile Ultra Pro II Needle Guides and Bracket

Device Description:

The iLook™ 25 Needle Guide Attachment and Bracket Assembly is an accessory to the iLook™ 25 Diagnostic Ultrasound System. The accessory is made up of a polymeric bracket designed in such a way to facilitate easy and secure attachment to the iLook™ 25 transducer. There are features on the bracket that prevent the bracket from being orientated incorrectly when attached to the transducer. The needle guide is a separate polymeric part that attaches to the bracket through a sterile sheath. Multiple needle guides are available corresponding to different depths that the clinician may need for guided needle placement into vascular or other anatomical structures. The needle guides will support various sized needles. The bracket and user guide are shipped separately from the needle guides. The sterile needle guide kit contains multiple needle guides, sterile sheath, ultrasound transmission gel, and bands.

Intended Use:

The intended use of the iLook™ 25 Needle Guide Attachment and Bracket Assembly when used in conjunction with the Ultrasound System and attached to the Ultrasound System's transducer is to facilitate proper needle placement to various depths in vascular or other anatomical structures from the transducer surface

Technological Characteristics Comparison:

A comparison of the iLook™ 25 Needle Guide Attachment and Bracket Assembly to its predicate devices show similarities and some differences. The brackets in all cases are polymeric devices that attach to or are part of an ultrasound transducer. The brackets in all cases are not sterile and will be covered with a sterile sheath prior to use. These brackets are designed to accept and retain the needle guides in a mechanically secure way through the medium of the sterile sheath. The needle guides are separate sterile polymeric parts that are offered in different sizes, or a single size that may fit on a multi-angled bracket. Separate sizes correspond to the different depths that the clinician may need for accurate guided needle placement. The needle guides are sold in sterile kits that contain multiple needle guides, sterile sheath, ultrasound transmission gel, and bands.

Testing:

Testing on the iLook™ 25 Needle Guide Attachment and Bracket Assembly involved laboratory tests which demonstrated that the labeled depth for the needle guides was accurate within a specified tolerance when attached to the Bracket and iLook 25 transducer enclosure. This testing was done using a mechanical fixture and, separately, a ultrasound phantom contain holes at specified depths in a permeable membrane.

Additionally, the iLook™ 25 Needle Guide Attachment and Bracket Assembly met biocompatibility requirements specified by ISO 10993-01 and FDA Memorandum #G95-1 for their classification. Environmental, packaging, shipping, shelf life, and sterilization requirements were met through validations performed by the contract manufacturer.

Conclusion:

The testing described above supports the conclusion that the iLook™ 25 Needle Guide Attachment and Bracket Assembly should be substantially equivalent to the safety and effectiveness demonstrated by the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 2003

SonoSite, Inc.
% Mr. Mark Job
510(k) Program Manager
TÜV Product Service
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K030064
Trade/Device Name: iLook™ Needle Guide Attachment and Bracket Assembly
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 ITX
Dated: January 6, 2003
Received: January 7, 2003

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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K030064

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: iLook™ 25 Needle Guide Attachment and Bracket Assembly

Indications for Use:

The intended use of the iLook™ 25 Needle Guide Attachment and Bracket Assembly when used in conjunction with the Ultrasound System and attached to the Ultrasound System's transducer is to facilitate proper needle placement to various depths in vascular or other anatomical structures from the transducer surface.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030064

Prescription Use ✓

(Optional Format 3-10-98)