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OCT 1 9 2004

# 510(k) Summary
# Site~Rite® Needle Guide Kits and Site~Rite® Probe Cover Kit

Common/Classification Name: Diagnostic Ultrasound Transducer,
21 CFR 892.1570

Bard Access Systems
5425 West Amelia Earhart Drive, Salt Lake City, UT 84116
(801)595-5534 – (801)595-5425 (Fax)

Contact: Charles Morreale; Prepared: September 3, 2004

## A. LEGALLY MARKETED PREDICATE DEVICES

The Site~Rite Needle Guide Kits and Probe Cover Kit are substantially equivalent to the Site~Rite Needle Guide (K931403) and the Protek Medical Products, Inc. Ultrasound Transducer Drape Kit. (K970889).

## B. DEVICE DESCRIPTION

Site~Rite Needle Guide Kits - Single use sterile disposable needle guide kit available in 18 GA., 20 GA. and 21 GA. configurations. Each kit contains; 1 set of needle guides, conductive gel, elastic bands and a polyethylene sheath.

Site~Rite Probe Cover Kit – Single use sterile disposable sheath kit. Each kit contains; conductive gel, elastic bands and a polyethylene sheath.

## C. INTENDED USE

Site~Rite Needle Guide Kits and Site~Rite Probe Cover Kits are intended to be used with Site~Rite Ultrasound Systems. The probe cover sheathes the transducer and isolates a site of surgical penetration from microbial and other contamination. The needle guide provides guidance for a needle to intersect an ultrasound beam at a fixed distance below the skin to assist the medical practitioner in placing the tip of a needle in a specific structure.

## D. SUBSTANTIAL EQUIVALENCE SUMMARY

The Site~Rite Needle Guide Kits and Site~Rite Probe Cover Kit have identical indications for use as the Site~Rite Needle Guide –K931403 and Ultrasound Transducer Drape Kits, Polyethylene. The characteristics of the components within the predicate device are the same as the predicate device. The primary modifications are suppliers, manufacturing changes and to incorporate the product into Bard Access Systems design control and sterilization methods.

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## E. TECHNOLOGICAL CHARACTERISTICS

There are no changes made that affect the technological characteristics of the device.

## F. TESTING

Testing was carried out to address the requirements associated with the required 510(k) information Based on March 12, 2000 Guidance for Manufacturers Seeking Marketing Clearance of Ear, Nose, and Throat Endoscope Sheaths Used as Protective Barriers. (This guidance is referenced for ultrasound accessories on the FDA website, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm?panel=RA#TopPage, retrieved June 25, 2004.)

## G. CONCLUSIONS

This pre-market submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2004

Bard Access Systems, Inc.
% Mr. Robert Mosenkis
President
Citech
5200 Butler Pike
PLYMOUTH MEETING PA 19462-1298

Re: K042445
Trade/Device Name: Site-Rite Needle Guide Kits and Probe Cover Kit
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Regulatory Class: II
Product Code: 90 ITX
Dated: October 1, 2004
Received: October 4, 2004

Dear Mr. Mosenkis:

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 (Premarket Approval), it may be subject to such 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 this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 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

SEP - 8 2004

# Indications for Use

510(k) Number (if known): K042445

Device Name: Site~Rite Needle Guide Kits and Site~Rite Probe Cover Kit

Indications for Use:

Site~Rite Needle Guide Kits and Site~Rite Probe Cover Kits are intended to be used with Site~Rite Ultrasound Systems. The probe cover sheathes the transducer and isolates a site of surgical penetration from microbial and other contamination. The needle guide provides guidance for a needle to intersect an ultrasound beam at a fixed distance below the skin to assist the medical practitioner in placing the tip of a needle in a specific structure.

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 OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042445