NOV 10 1999

K993624

510(k) Summary

Site~Rite 3 Ultrasound Scanner

Common/Classification Name: Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560

Dymax Corporation
271 Kappa Drive
Pittsburgh, PA 15238

Contact: Charles Morreale; Prepared: October 18, 1999

A. LEGALLY MARKETED PREDICATE DEVICES

The Site~Rite 3 Ultrasound Scanner is substantially equivalent to the Site~Rite 2 Ultrasound Scanner (cleared as the Dymax Plus 1 Scanner, K862127) and the Dymax Plus 1 (cleared as the Dymax TM18, K850478).

B. DEVICE DESCRIPTION

The Site-Rite 3 pulsed echo ultrasound system is a lightweight, low-output, portable, real-time, B-mode, ultrasound scanner designed primarily to assist physicians in gaining vascular access to major veins and arteries. It is a unique scanner that offers high resolution imaging to the depth of 18 cm. Site-Rite is portable and thus easy to use at the bedside and in a variety of clinical scenarios: intensive care units, emergency rooms, operating rooms, angiography suites, catheterization laboratories, etc.

The Site-Rite 3 ultrasound scanner can be operated on battery or AC power. It utilizes only proprietary probes manufactured and currently marketed by Dymax, with frequencies ranging from 3.5 MHz to 9.0 MHz. Image depth depends on the choice of probe and ranges from a minimum of 0.5 cm with the 9.0 MHz probe to a maximum of 18 cm with the 3.5 MHz probe.

The disposable items, supplied in sterile packs, are currently marketed products.

C. INTENDED USE

The Site~Rite 3 ultrasound system with associated probes and accessories provide ultrasound imaging of vascular structures, various organs, and structures of the body. Ultrasound guidance for placement of

needles and catheters in these structures or organs may also be performed. The ultrasound guidance may occur either intraoperatively or percutaneously.

The Site~Rite 3 is not intended for opthalmic applications.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The Site~Rite 3 Ultrasound Scanner has similar, but not identical indications for use as the predicate devices. The Site~Rite 3 indications add specific vein access to the already cleared general vascular access indication. However, this difference clearly does not change the intended use.

The technological characteristics are somewhat different from the predicate devices since the electronics design of the Site~Rite 3 has included digital electronic technology, whereas the predicate devices were completely analog in nature. The transducers, however, are unchanged from the currently marketed products.

The differences in technological characteristics do not raise new types of questions of safety and effectiveness. There are standard methods for accessing safety and performance, primarily through the methods spelled out in the FDA guidance. Performance data are presented in the 510(k) and these data demonstrate equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

The primary difference in the Site~Rite 3 and the Site~Rite 2 is that the older Site~Rite 2 has a generator with an analog design, whereas the Site~Rite 3 is digital in design.

F. TESTING

Testing was carried out to address electrical safety, electromagnetic emissions, and acoustic output. Data from this testing demonstrate equivalence with the predicate devices.

Clinical studies carried out using the Site~Rite 2 device, which uses the same transducers and image processing algorithms, has shown the usefulness of the Site~Rite for needle placement in a number of different vascular and non-vascular applications. These studies are summarized and reports are included in the 510(k).

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

NOV 10 1999

Dymax Corporation
C/O Robert Mosenkis
CITECH
5200 Butler Pike
Plymouth Meeting, PA 19462-1298

Re: K993624
Site-Rite 3 Ultrasound System
Dated: October 22, 1999
Received: October 26, 1999

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the Site-Rite 3 Ultrasound System as described in your premarket notification:

Transducer Model Number

3.5 MHz, 5.9 MHz, 7.5 MHz, and 9.0 MHz

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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers."

If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your 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 market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Robert Phillips, Ph.D. at (301) 594-1212.

Sincerely yours,

for David A. Schultz

CAPT Daniel Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Site~Rite 3 Ultrasound Scanner

Indications For Use:

The Site~Rite 3 ultrasound system with associated probes and accessories provide ultrasound imaging of vascular structures, various organs, and structures of the body. Ultrasound guidance for placement of needles and catheters in these structures or organs may also be performed. The ultrasound guidance may occur either intraoperatively or percutaneously.

The Site~Rite 3 is not intended for opthalmic applications.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hoyer

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993624

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)