K993532

510K Summary of Safety and Effectiveness for DDS

DEC 15 1999

COMPANY INFORMATION:

Impax Technology Inc.,
455 Phillip Street,
Waterloo, Ontario
Canada
N2L 3X2

Phone: (519) 746-2900
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CONTACT:

Paula Pfeifle, Regulatory Affairs

DATE OF SUBMISSION:

October 18, 1999

DEVICE:

DEVICE NAME: DDS

TRADE/PROPRIETARY NAME: DS3000, RS3000, CS5000, OT3000, IS3000, RS5000, CD3000, US3000, (amongst other names)

COMMON NAME: Diagnostic Review Station

CLASSIFICATION NAME: System, Image Processing

DEVICE DESCRIPTION AND INTENDED USE:

DDS software is combined with appropriate hardware to form a diagnostic review station. DDS is used to display and manipulate patient images and demographic information, for diagnostic, review and referral purposes. It is a software package which may be marketed as a software only solution, or in conjunction with standard hardware. DDS can be used as a stand-alone system or in connection with a larger system.

SUBSTANTIAL EQUIVALENCE DEVICE:

Radworks Medical Imagining Software with Quality Control Module

SUBSTANTIAL EQUIVALENCE TECHNOLOGICAL COMPARISON:

Both DDS and Radworks are sold as software packages which can be used on standard PC hardware with Windows NT, and the DDS can also be used on standard Unix hardware with Solaris.

Both systems can query, retrieve, and transmit medical images over phone lines or networks. Both systems provide high quality display capability. Both systems allow digital processing, measurement and annotation of images.

SUBSTANTIAL EQUIVALENCE NON-CLINICAL PERFORMANCE AND TEST DATA:

Software testing follows standard procedures: test plans are developed, testing is carried out through a variety of automated and manual testing, and test results are recorded and reported. The DDS software has been extensively tested by programmers, quality assurance specialists, and potential customers.

SUBSTANTIAL EQUIVALENCE CONCLUSIONS:

Impax Technology Inc. concludes that the intended use for the DDS is that same as that of the predicate device, and that the technological characteristics demonstrate that they are equivalent to the predicate device. Thus, this premarket notification has demonstrated Substantial Equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 5 1999

Paula Pfeifle
Regulatory Affairs
Impax Technology, Inc.
455 Phillip Street
Waterloo, Ontario
Canada N2L 3X2

Re: K993532
DDS Software (Diagnostic Image Review Station)
Dated: October 18, 1999
Received: October 19, 1999
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Ms. Pfeifle:

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.

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

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

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

Enclosure

Statement of Indications of Use

510(k) Number: K993532

Device Name: Impax Technology Inc., DDS

Indications for Use:

DDS software is combined with appropriate hardware to form a diagnostic review station. DDS is used to display and manipulate patient images and demographic information, for diagnostic, review and referral purposes. It is a software package which may be marketed as a software only solution, or in conjunction with standard hardware. DDS can be used as a stand-alone system or in connection with a larger system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993532

Prescription Use √
(Per 21 CFR 801.109)

Over the Counter Use _____