K130406
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VIDAR systems corporation
A.3D Systems Company

APR 2 9 2013

510(k) Summary

Submitter: VIDAR Systems Corporation
365 Herndon Parkway
Herndon, VA 20170 U.S.A.
703-471-7070 (phone)
703-471-1165 (fax)

Official Correspondent: Carrie L. Brancart

Date of Submittal: 2/12/13

Trade Name: DiagnosticPRO *Edge*

Common Name: X-Ray Film Digitizer

Classification Name: Medical Image Digitizer (21CFR892.2030)

Product Code: LMA
Predicate Device: Trade Name: DiagnosticPRO M, Mammography PRO
510(k): K993598

Manufacturer: VIDAR Systems Corporation

Device Description:

The device consists of a film digitizer with multi-film feeder, external power adapter, and Windows driver software. The film digitizer will convert the X-ray film into digital data representing the X-ray film, and the windows driver software is used to import the digital data into a compatible software application. The digitizer is used with DICOM standard software that meets or exceeds ACR and DICOM standards for use of secondary capture images for consultation, review and final interpretation.

The digitizer is connected to a PC through a USB 2.0 interface. The digitizer utilizes rollers driven by a stepper motor to feed the X-ray film past the scan optics. The scan optics consists of a white LED illuminator, a lens, mirrors, and a CCD linear array detector.

This device has no patient contact and does not supply a diagnostic result. The film digitizer only provides digital data representing the film.

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Intended Use:

The DiagnosticPRO *Edge* digitizer is used for making digital copies of medical x-ray film, including printed and radiographic film. The target users of these devices are medical professionals or trained staff for use as secondary capture images for consultation, review and final interpretation.

The devices are indicated for the digitization of mammography images for review and analysis, but not as the sole basis for screening or diagnosis.

Technological Characteristics:

The VIDAR DiagnosticPRO *Edge* film digitizer offers a high optical resolution of 600 dpi; 16-bit grayscale, optical density sensitivity (DMAX) of 5.5 OD, and a medical OD range of 0.1 – 4.0 (incorporates noise and linearity measurements).

Performance Testing:

VIDAR conducts extensive performance testing and the test results demonstrate the device meets the requirements for its intended use. Please see Section 19 Bench Testing.

Substantial Equivalence to Predicate Device:

The DiagnosticPRO *Edge* is substantially equivalent to the VIDAR DiagnosticPRO M, and Mammography PRO film digitizers. The comparison table of the principal characteristics of the two devices is shown in Section 13 and specification data for the DiagnosticPRO *Edge* is included in Section 12.

Conclusion:

In terms of intended use, function, safety, operating environmental conditions and effectiveness of the DiagnosticPRO *Edge* it is determined to be substantially equivalent to the predicate device used for this application.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 29, 2013

VIDAR Systems Corporation
% Ms. Carrie L. Brancart
Director, Quality Assurance and Regulatory Affairs
365 Herndon Parkway
HERNDON VA 20170

Re: K130406
Trade/Device Name: DiagnosticPRO *Edge*
Regulation Number: 21 CFR 892.2030
Regulation Name: Medical Image Digitizer
Regulatory Class: II
Product Code: LMA
Dated: February 19, 2013
Received: February 22, 2013

Dear Ms. Brancart:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130406

Device Name: DiagnosticPRO *Edge*

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

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

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