

TRADITIONAL 510(K) SUBMISSION

Submission Date: February 14, 2007
(Month/dd/yyyy)

Name & Address of BSI Authorized Person:

John Howlett,
Head of BSI Medical Device Notified Body,
BSI Group, Product Services,
British Standards Institution,
Maylands Avenue,
Hemel Hempstead, Herts HP2 4SQ
UK

Phone: 011- 44-1442-278507
FAX: 011-44-1442-278575

Name & Address of BSI Technical Reviewer:

Andre Routh, PhD.,
Senior Product Expert,
BSI Product Services – Healthcare,
12110 Sunset Hills Road, Suite 200
Reston, VA 20190

Phone/FAX: 609-654-1600

Name & Address of 510(K) Submitter:

Carrie L. Brancart
VIDAR Systems Corporation
365 Herndon Parkway
Herndon, VA 20170

Phone: 703-471-7070
FAX: 703-471-1165

Date received: February 05, 2007

Device Trade Name: VIDAR Vision 2000

Device Common Name: Digital Radiography Image Acquisition System

FDA Classification:

Device Class: II
Panel: Radiology
Product Code: MQB
Regulation Number: 892.1650
Device: Solid state x-ray imager (flat panel/digital imager)

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Tab 1 - Cover Letter Traditional 510(k)

Consultation with FDA Branch Chief, Team Leader or Designate

Andre Routh, the BSI Technical Reviewer, spoke with Dr. Robert Phillips (Supervisory Physicist, DHHS/ FDA/ CDRH/ ODE/ DRARD/ RDB) on January 25, 2007 to identify relevant issues and review criteria. Dr. Routh had previously sent an email introducing himself and the VIDAR Vision 2000 system (January 22, 2007). During the discussion, Dr. Phillips suggested that VIDAR request a letter from IMIX (Tampere, Finland) permitting VIDAR to include by reference the data submitted by IMIX to FDA in K974863. Unfortunately, the agreement between VIDAR and IMIX did not extend to the exchange of such information so the present submission follows the Traditional 510(k) format.

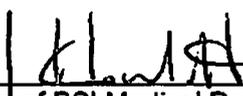
BSI Recommendation Regarding Substantial Equivalence:

The VIDAR VISION 2000 is currently manufactured by IMIX-ADR(Tampere, Finland) under the Premarket Notification of the predicate device (K974863). VIDAR intends to market this device under its own name. The device is physically and electrically (including software) identical to the predicate.

The labeling for the subject device has been reviewed to verify that the indication/intended use for the device is unaffected.

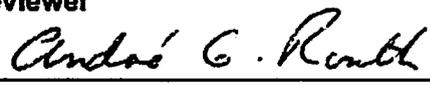
Based on the evidence supplied by the submitter, I recommend the device be determined substantially equivalent to the previously cleared device.

BSI Authorized Person

Signature: 
John Howlett, Head of BSI Medical Device Notified Body

Date: February/22/2007
(Month/dd/yyyy)

BSI Technical Reviewer

Signature: 
Andre G. Routh, PhD, Senior Product Expert

Date: Feb 14, 2007
(Month/dd/yyyy)



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

Vidar Systems Corporation
% Mr. John Howlett
British Standards Institution
Product Services
Maylands Avenue
HEMEL HEMSTEAD HP2 4SQ
UNITED KINGDOM

AUG 23 2013

Re: K070563
Trade/Device Name: VIDAR Vision 2000
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: February 14, 2007
Received: February 27, 2007

Dear Mr. Howlett:

This letter corrects our substantially equivalent letter of March 16, 2007.

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

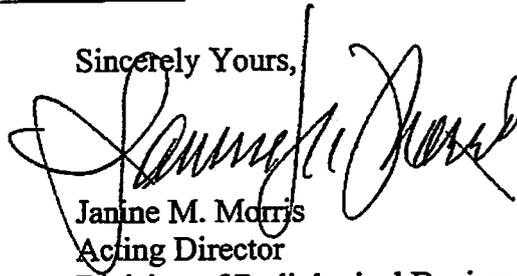
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html>.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070563

Device Name: VIDAR Vision 2000

Indications For Use:

"The VIDAR Vision 2000 is indicated for use in generating radiographic images of human anatomy. It is a Solid State X-ray Imaging system intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures.

The VIDAR Vision 2000 is not indicated for diagnostic X-ray mammography."

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 IF 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 K070563

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