



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Ariel Marciano  
Director, Operations  
Meridian Medical Systems, LLC  
325 Harris Drive  
AURORA OH 44202

MAY 22 2012

Re: K112527  
Trade/Device Name: Universal Digital Interface (UDI) 1717  
Regulation Number: 21 CFR 892.1680  
Regulation Name: Stationary x-ray system  
Regulatory Class: II  
Product Code: MQB  
Dated: April 17, 2012  
Received: April 17, 2012

Dear Ms. Marciano:

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.

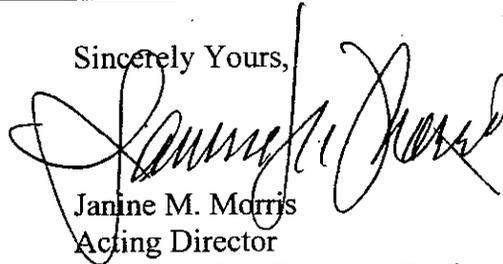
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

**4. INDICATION FOR USE**

**Applicant:** Meridian Medical Systems

**510(k) Number (if known):** \_\_\_\_\_ K112527 \_\_\_\_\_

**Device Name:** Universal Digital Interface (UDI) 1717

**Indication For Use:** The UDI 1717 System is a Direct Digital Radiography Upgrade unit used to directly capture and convert conventional projection images from an X-ray source to digital images. The result is a diagnostic image, viewable on a computer monitor, without the time and costs involved with film or cassette handling. The image can be further manipulated on the computer monitor via imaging software, can be printed and/ or e-mailed. The UDI 1717 unit provides Digital Radiographic (DR) images for every general radiographic application in hospitals, clinics and imaging centers. The 17" x 17" sensor plate capture large patient imaging and areas.

For the review of parts of the anatomy (legs, spine, etc.) that exceed the panel's dimensions, several Images can also be "stitched" together to allow the review of this part of the anatomy as one single image.

The UDI 1717 cannot be used for Mammography applications.

Prescription Use X  
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use \_\_\_\_\_  
(21 CFR Part 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE).

  
Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K112527