K111833

5. 510(K) SUMMARY

Diagnosoft, Inc.
Virtue
(per 21CFR 807.92)

SEP 2 1 2011

1. SUBMITTER/510(K) HOLDER

Diagnosoft, Inc.
6501 Weston Parkway
Suite 125
Cary, NC 27513

Contact Person: Firas BenAchour
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Date Prepared: June 23, 2011

2. DEVICE NAME

Proprietary Name: Virtue
Classification Name: Picture archiving and communications system

3. PREDICATE DEVICE

- Philips Easy Vision Workstation Release 6 marketed by Philips Medical Systems, K023137
- Harp 2.06 marketed by Diagnosoft, Inc., K100352

4. DEVICE DESCRIPTION

The Diagnosoft Virtue is software that runs on Windows-based operating systems to view and analyze MR images of the heart in DICOM format.

5. INTENDED USE

The Virtue software receives image data from medical scanning devices, such as CT or MRI, or from image archives and performs viewing, image manipulation, communication, printing and quantification of images.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The characteristics of the Virtue are substantially equivalent to the following current legally marketed predicate devices based on intended use, typical clinical use, and operational and fundamental technological characteristics.

- Philips Easy Vision Workstation Release 6 marketed by Philips Medical Systems, K023137
- Harp 2.06 marketed by Diagnosoft, Inc., K100352

A detailed side-by-side comparison of the Virtue with the identified predicate device is provided in the substantial equivalence discussion in this premarket notification.

7. PERFORMANCE TESTING

Testing of the Virtue software has demonstrated that the device fulfills prospective defined performance criteria and that the device meets the user needs.

8. CONCLUSION

Based on the similarities in indication for use, design, functional, and operational features the Virtue has demonstrated substantial equivalence to the listed legally marketed predicate device and any differences do not affect the product's safety or effectiveness.

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

Diagnosoft, Inc.
% Mr. Jeffrey Roberts
Medical Device Consultants
40 Plain Street
NORTH ATTLEBORO MA 02760

SEP 21 2011

Re: K111833
Trade/Device Name: Virtue
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 23, 2011
Received: June 28, 2011

Dear Mr. Roberts:

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,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) Number (if known): Not yet assigned

Device Name: Virtue

Indications for Use:

The Virtue software receives image data from medical scanning devices, such as CT or MRI, or from image archives and performs viewing, image manipulation, communication, printing and quantification of images.

Prescription Use _X_ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111833