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510(K) SUMMARY

JAN 30 2014

A. Manufacturer:	NDS Surgical Imaging, LLC 5750 Hellyer Avenue San Jose, CA 95138 USA
B. Submitted By:	Jim Leng Regulatory Engineer/NDS Surgical Imaging, LLC
B1, Address:	NDS Surgical Imaging, LLC 5750 Hellyer Avenue San Jose, CA 95138 USA
C. Date of Preparation:	July 18, 2013
D. Contact Information:	Tel: 408-776-0085 Fax: 408-776-9878
E. Classification:	Picture Archiving Communication System
F. Common Name:	System, Image Processing, Radiological
G. Proprietary Name:	The Dome® S10 Color Monitor
H. Classification Number:	21 CFR 892.2050
I Product Code:	LLZ
J. Substantial Equivalence:	Model S10 is substantial equivalent to the predicate device K093197 Coronis Fusion 10MP (MDCG-10130). Both devices have the same indication for use with the same characteristics. Both devices use same technology and use displays with the same resolution, same number of colors, same refresh rate, same maximum brightness, and the same pixel rise/fall times. The few minor cosmetic differences do not impact display information and viewing.
K. Device Description:	The Dome S10 is a widescreen 30 –inch 10 megapixel grayscale diagnostic monitor. Its sleek design and high brightness makes the S10 ideal for viewing full field digital mammography and allow it to show two 5MP images for back-to-back chest wall reads.

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L. Intended Use:	The Model S10 is intended for use in displaying and viewing radiography images for review and analysis by trained medical practitioners, and for use in mammography display systems.
M. Technological Characteristics:	Bezel-free framing of 10 megapixels of data is presented in a landscape format with resolution of 4096 x 2560 and a pixel pitch of 0.158mm. 1024 intrinsic shades of gray with programmable gamma yield a palette of up to 4096 shades. The integrated Dome RightLight Controller monitors and stabilizes backlight luminance. The display unit includes a PCI Express graphics board to support the required dual-link connectivity for the display.
N. Conclusion:	Based upon our test results, the model S10 radiology display meets IEC/EN60601-1 and 60601-1-2 standards which establish its safe design and operation. And both the model S10 and the predicate device Coronis Fusion 10MP (MDCG-10130) are identical in terms of indication for use, characteristics, specifications and performance.

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

January 30, 2014

NDS Surgical Imaging, LLC
% Mr. Jim Leng
Regulatory Engineer
5750 Hellyer Avenue
SAN JOSE CA 95138

Re: K132770
Trade/Device Name: Dome S10
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 16, 2014
Received: January 22, 2014

Dear Mr. Leng:

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.

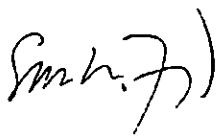
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)* K132770

Digital Flat-Panel Display System, Model: S10

Indications for Use *(Describe)*

The Model S10 is intended for use in displaying and viewing radiography images for review and analysis by trained medical practitioners, and for use in mammography display systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995

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