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

May 26, 2016

NDS Surgical Imaging, LLC.
Mr. Jim Leng
Regulatory Engineer
5750 Hellyer Ave
San Jose, California 95138

Re: K161228
Trade/Device Name: Radiance Ultra Series Zerowire Embedded
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 14, 2016
Received: May 2, 2016

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 and Part 809), please contact the Division of Industry and Consumer Education 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" (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 Industry and Consumer Education 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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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 below.

510(k) Number *(if known)*
K161228

Device Name
Radiance Ultra Series ZeroWire Embedded

Indications for Use *(Describe)*
The Radiance Ultra series ZeroWire Embedded and ZeroWire G2 is a paired wireless video communication transmitter and receiver, intended for delivery of video signals from a source such as an endoscopy camera/processor, or other video source over a radio-frequency link to a ZeroWire Receiver for display of images during endoscopic and general surgical procedures. The Radiance Ultra series ZeroWire Embedded and ZeroWire G2 wireless video system is a non-sterile reusable device not intended for use in the sterile field

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

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:	May 24, 2016
D. Contact Information:	Tel: 408-776-0085 Fax: 408-776-9878
E. Classification:	Endoscope and Accessories
F. Common Name:	Wireless Displays
G. Proprietary Name:	Radiance Ultra series ZeroWire Embedded
H. Classification number:	21 CFR 876.1500
I Product Code:	GCJ
J. Substantial Equivalence:	Predicate device K151609 model ZeroWire G2
K. Device Description:	Radiance Ultra series ZeroWire Embedded monitors are designed with an integrated wireless video receiver module (Rx), enabling the reception of a video signal over a radio frequency link instead of a video cable. These monitors are designed for use in non-sterile healthcare environments. The Radiance Ultra series ZeroWire Embedded is a medical grade wireless video streaming device pair. The external transmitter (Tx) unit is designed to be mounted on a primary display, on an endoscopic cart, or any other elevated location in close vicinity to the video

source. The Tx unit obtains its video input signal from either the loop through output of the primary display, or directly from the video source. The Tx unit will accept video in either HDMI/DVI or SDI formats up to 1920 x 1080p 60 Hz resolution. The Tx unit is powered by a NDS 12-24V DC-DC power converter while the Rx module shares the same 24V DC input of the display.

Radiance Ultra series ZeroWire Embedded Models
Radiance Ultra 24 ZeroWire Embedded
Radiance Ultra 27 ZeroWire Embedded
Radiance Ultra 32 ZeroWire Embedded
Radiance Ultra 55 ZeroWire Embedded

L. Indications for Use:

The Radiance Ultra series ZeroWire Embedded and ZeroWire G2 is a paired wireless video communication transmitter and receiver, intended for delivery of video signals from a source such as an endoscopy camera/processor, or other video source over a radio-frequency link to a ZeroWire Receiver for display of images during endoscopic and general surgical procedures. The Radiance Ultra series ZeroWire Embedded and ZeroWire G2 wireless video system is a non-sterile reusable device not intended for use in the sterile field.

M. Technological Characteristics:

Radiance Ultra series' ZeroWire Embedded are the most advanced medical grade wireless video transfer solution for minimally invasive surgery and interventional procedures. The ZeroWire product was released with the RF platform based on the Silicon Image 60 GHz 3rd generation Sil6310 / Sil6320 WirelessHD HRTX chipset and Sil6310 / Sil6321 WirelessHD HRRX chipset. By utilizing directional antenna and beam forming in the 60 GHz frequency spectrum, the pair provides a robust narrow-beamed wireless video link to minimize the interference with other devices. Inside the Rx Radiance Ultra series ZeroWire embedded, it still has the same functional partition: a Rx RF module followed by a Rx adapter providing an on-screen display engine to show video messages and RSSI strength bars as a visual interface of the wireless link status to the end user. Radiance Ultra ZeroWire Embedded enhances safety in the OR by eliminating the need for a video cable. The proprietary

memory-enabled pairing mechanism makes installation quick and easy. Radiance series ZeroWire Embedded displays technology provides the highest quality of service and is specifically designed for the video transmission challenges of the surgical environment.

N. Performance:

Based upon our design, the Radiance Ultra series' ZeroWire Embedded displays meet and exceed IEC 60601-1, ANSI/AAMI ES60601-1, IEC 60601-1-2 and FCC part 15. The displays have successfully passed design validation to further demonstrate their safety and effectiveness.

O. Conclusion:

Based upon results from the design verification, Radiance Ultra series' ZeroWire Embedded displays demonstrate performance, safety, and effectiveness that are equivalent to the predicate device – predicate device K151609 model ZeroWire G2 in its system operation.