October 19, 2022

NDS Surgical Imaging, LLC.
Jim Leng
Sr. Regulatory Engineer
100 Paramount Drive, Suite 101
Sarasota, Florida 34232

Re: K222890
Trade/Device Name: Radiance Ultra 32" 4k Zerowire Duo
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 16, 2022
Received: September 23, 2022

Dear Jim 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222890

Device Name
RADIANCE ULTRA 32" 4K ZEROWIRE DUO

Indications for Use *(Describe)*
The Radiance Ultra 32" 4K ZeroWire Duo 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 32" 4K ZeroWire Duo 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.

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

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510(K) SUMMARY

A. Manufacturer:
NDS Surgical Imaging, LLC
100 Paramount Drive, Suite 101
Sarasota, Florida 34232
USA

B. Submitted By:
Jim Leng
Sr. Regulatory Engineer/NDS Surgical Imaging, LLC

B1, Address:
NDS Surgical Imaging, LLC
100 Paramount Drive, Suite 101
Sarasota, Florida 34232, USA

C. Date of Preparation:
October 19, 2022

D. Contact Information:
Tel: 408-310-0832

E. Classification:
Endoscope and Accessories

F. Common Name:
Wireless Displays

G. Proprietary Name:
RADIANCE ULTRA 32" 4K ZEROWIRE DUO

H. Classification number:
21 CFR 876.1500

I Product Code:
GCJ

J. Substantial Equivalence:
Predicate device K161228 model Radiance Ultra series ZeroWire Embedded and,

Predicate device K151609 model ZeroWire G2

	Zero Wire G2	Radiance Ultra 27” ZeroWire Embedded	Changes : Radiance Ultra 32" 4K ZeroWire Duo
General:			
K Number	K151609	K161228	**TBD**
Product Class	Class II	Same	Same
Product Code	GCJ	Same	Same
Device Name (FDA)	Laparoscope, General & Plastic Surgery	Same	Same
Regulation Description	Endoscope and accessories	Same	Same

Indications for Use	The NDS 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 ZeroWire G2 wireless video system is a non-sterile reusable device not intended for use in the sterile field.	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	The Radiance® Ultra 32" 4K ZeroWire Duo 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 videos during endoscopic and general surgical procedures. The Radiance® Ultra 32" 4K ZeroWire Duo is a non-sterile reusable device not intended for use in the sterile field.
Where Used	Medical Facility	Same	Same
Compatibility with environment and other devices	IEC 60601-1-2	Same	Same
Design Specifications:			
Frequency Spectrum	59.40 to 63.56 GHz	Same	Same
Time Frequency Coding	No	Same	Same
Antenna beam forming	Yes	Same	Same
Number of Channels	6	Same	Same
RF Power out (Max)	28 dBmi	Same	Same
Tx/Rx range	≤ 30ft (9.1m)	Same	Same
RF Bandwidth	1.76 GHz per channel (HRP Bandwidth), 92 MHz per channel (LRP Bandwidth)	Same	Same
Video Formats	up to 1920 x 1080 @ 60 Hz	Same	up to 3840x2160 @60 Hz
System Latency	less than 1 frame	Same	Same
Video Input	DVI +3G-SDI	Multiple outputs include DVI +3G-SDI	Same
Tx/Rx pairing	single Tx-Rx pair	Same	Same
Tx/Rx pairing memory	Pairing is lost when power is removed	Same	Will retain pair information
Weight, Tx/Rx pair	500g	8.9 kg (19.5 lbs)	14.5 Kg (32.0 lbs.)
Operating Temperature	32 – 104°F (0-40°C)	Same	Same

Storage Temperature	-4 - 140°F (-20 - 60°C)	-20 to 50°C	Same
Relative Humidity (non-condensing)	< 70% RH(Non-condensed)	5 to 85%	10 to 90%
Display Size	N/A	27”	32”
Maximum Luminance1 (cd/m2, typical)	N/A	900	700
Native Resolution	N/A	1920 x 1080	3840 x 2160
Contrast Ratio (nominal)	N/A	1000:1	1350:1
Dot Pitch (mm)	N/A	0.311	0.1845
Vertical and Horizontal Viewing Angle	N/A	178°	same
Advance Encryption Standard for data communication security	256-bit AES Encryption	Same	Same
Input Signals	DVI-D, SDI	DVI-D, HD15, RGB/Component, Y/C, Composite SDI 4:2:2 (optional) HD/D1-SDI (optional) NTSC/PAL :Y/C, Composite (optional) Analog Component (optional) 3G/HD/SD-SDI (optional) DVI-D (optional)	12G-SDI DVI-D DisplayPort DisplayPort Tx HDMI USB Mini B USB Micro AB
Output Signals	DVI	Composite output connector Y/C output connector RGB/component output connectors External synchronized output connector	12G-SDI DVI-D
Sterility and Safety:			
Sterility	Non-sterile	Same	Same
Mechanical Safety	N/A	Same	Same
Chemical Safety	N/A	Same	Same
Electrical Safety	IEC 60601-1	Same	Same
Radiation Safety	N/A	Same	Same

Standards:			
Safety	IEC/EN 60601-1	Same	Same
EMC	IEC/EN 60601-1-2; FCC CFR 47 Part 15	Same	Same

K. Device Description: Radiance Ultra 32" 4K ZeroWire Duo is a medical LCD display designed to both wirelessly receive or transmit video signal with up to 4K resolution over a radio frequency link to a partner display.

L. Indications for Use: The Radiance® Ultra 32" 4K ZeroWire Duo 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 32" 4K ZeroWire Duo is a non-sterile reusable device not intended for use in the sterile field.

M. Technological Characteristics: Radiance Ultra 32" 4K ZeroWire Duo is the most advanced medical-grade wireless video transfer solution for minimally invasive surgery and interventional procedures. By utilizing a directional antenna and beam forming in the 60 GHz frequency spectrum, the displays provide a robust directed wireless video link to minimize interference with other devices. Radiance Ultra 32" 4K ZeroWire Duo enhances safety in the OR by eliminating the need for a video cable. The proprietary memory-enabled pairing system in a LCD display makes installation quick and easy. Radiance Ultra 32" 4K ZeroWire Duo display 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 32" 4K ZeroWire Duo display meets and exceeds IEC 60601-1, ANSI/AAMI ES60601-1, IEC 60601-1-2 and FCC part 15.

The display has successfully passed design validation to further demonstrate its safety and effectiveness.

O. Conclusion:

Based upon results from the design verification, Radiance Ultra 32" 4K ZeroWire Duo display demonstrates performance, safety, and effectiveness that are equivalent to the predicate devices – predicate device K151609 model ZeroWire G2 and Predicate device K161228 The Radiance Ultra series ZeroWire Embedded in its system operation.