DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 7, 2017

NDS Surgical Imaging, LLC.
% Ms. Shelley Trimm
RCQ Consulting Services
1152 Navarro Street
Santa Rosa, California 95401

Re: K170598
Trade/Device Name: ZeroWire Mobile
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: February 23, 2017
Received: March 1, 2017

Dear Ms. Trimm:

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 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,

Jennifer R. Stevenson -S

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)*

K170598

Device Name
ZeroWire Mobile

Indications for Use *(Describe)*

The ZeroWire Mobile, Radiance Ultra series ZeroWire Embedded, and ZeroWire G2 are a paired video communication transmitter and receiver, intended for delivery of medical video signals from a source such as an endoscopy camera/processor, or other video source over a radio-frequency link to a video for review and analysis of medical images during endoscopic and general surgical procedures.

The ZeroWire Mobile, Radiance Ultra series, and ZeroWire G2 wireless video systems are non-sterile reusable devices 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 5750 Hellyer Avenue San Jose, CA 95138 USA
B. Submitted By:	Shala Famil Sr. Director QA/RA, NDS Surgical Imaging, LLC
B1. Address:	NDS Surgical Imaging, LLC 5750 Hellyer Avenue San Jose, CA 95138 USA
C. Date of Preparation:	February 23, 2017
D. Contact Information:	Tel: 408-912-0528 Fax: 408-705-5521
E. Classification:	Endoscope and Accessories
F. Common Name:	Wireless Displays
G. Proprietary Name:	ZeroWire Mobile Model Number: 90Z0160
H. Classification number:	21 CFR 876.1500
I Product Code:	GCJ
J. Substantial Equivalence:	Predicate device: K151609 Model ZeroWire G2 Duo Predicate device: Special K161228 Model ZeroWire Radiance Ultra Series Display Monitors

K. Device Description:

ZeroWire Mobile is a medical grade, battery powered pole stand that eliminates the need for a power cord. It will be used as an accessory, secondary monitor display in Endo/GI procedure rooms, surgical operating rooms, or other clinical settings. ZeroWire Mobile is a cordless stand with a wireless monitor solution that provides the procedure or operating room with a mobile second display monitor eliminating the risk of biohazard contamination of cords and cables, and cable/cord trip hazards. The

ZeroWire Mobile is the second accessory to ZeroWire Duo Wireless HD Video Transfer System G2/ ZeroWire G2 Duo (K151609). The first accessory to be approved was the Radiance Ultra ZeroWire Embedded (Special K161228).

L. Indications for Use:

The ZeroWire Mobile, the Radiance Ultra Series ZeroWire Embedded, and ZeroWire G2 are a paired video communication transmitter and receiver, intended for delivery of medical video signals from a source such as an endoscopy camera/processor, or other video source over a radio-frequency link to a video for review and analysis of medical images during endoscopic and general surgical procedures.

The ZeroWire Mobile, Radiance Ultra Series and ZeroWire G2 Duo wireless video systems are non-sterile reusable devices not intended for use in the sterile field.

M. Technological Characteristics:

The ZeroWire Mobile consists of a 5-wheel mechanical stand to hold a display monitor, up to 32" in size and / or $\leq$ 33 lbs in weight, with 2 mounted power modules as DC power supply source for the monitor. The system is completed with a 4-bay wall-mount charger, allowing to charge 4 power modules simultaneously.

Three keys elements of the ZeroWire Mobile stand are the mechanical stand it-self, the DC –DC converter plus battery hot-swap monitoring circuitry, and the firmware allowing the user to interface and monitor the battery status.

Since the power module supply output can vary from 20V to 25V and a 24V +/- 5% output is required to power the monitor, there is a need for a DC-DC converter to regulate the DC output voltage. The system can run with either one or both power modules mounted and replacement of the drained power module shall not affect the voltage output of the running power module.

Characteristics:

- ZeroWire Mobile stand column has an adjustable height from 55 inches to 71 inches.

- Tiltable Vesa mount supporting a display up to 32” in size and / or 33 lbs of weight.
- 5-leg wheel base to provide maximum stability.
- Castors of 5-inch diameter and with an individual lock.

N. Performance:

The performance standards reports that the ZeroWire Mobile, Power Module, and 4-Bay charger are compliant to are available in Tab 11. The ZeroWire Mobile, ZeroWire G2 Duo Wireless Video System (K151609) and the Radiance Ultra ZeroWire Embedded monitor displays (Special K161228) as a system has successfully passed design verification testing to further demonstrate safety and effectiveness.

The following is a summary of standards have been tested to and passed:

ZeroWire Mobile

Standards
IEC 60601-1:2005=Corr.1(2006) + Corr.2 (2007) EN 60601-1:2006
IEC60601-1 3rd Edition (2005)
CAN/CSA-C22.2 No. 60601-1-08 (R2013) ANSI/AAMI ES60601-1:2005+A2 (R2012)
EN 60601-1-2:2007/AC:2010; FCC Part 15B Class B

ZeroWire Power Module

Document Type
Test Report - Batteries
IEC 62133:2012 EN 62133:2013
IEC 62133:2012 EN 62133:2013
File MH61123, Vol. 1
IEC 62133(ed.2) EN 62133:2013

4 Bay Charger

Standards
IEC 60601-1:2005+ CORR. 1:2006+ CORR. 2:2007 + AM1:2012 (or UEC 60601-1:2012 reprint)
IEC 60601-1:2005+ CORR. 1:2006+ CORR. 2:2007 + AM1:2012 (or UEC 60601-1:2012 reprint)

CAN/CSA-C22.:2007 2 No.60601-1:14 ANSI/AAMI ES60601- 1:2005+A2 (R2012)+A1
IEC 60601-1:2005+A1 IEC 60601-6:2010+A1 IEC 62366-2007+A1
EN60601-1-2: 2007/AC: 2010 Class B, FCC Part 15 Subpart B

Radiance 27" Embedded Display Monitor with ZeroWire Mobile

Standards
IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007), EN 60601-1:2006
IEC 60601-1, 3rd Edition (2005)
ANSI/AAMI ES60601- 1:2005+A2 (R2012) CAN/CSA-C22.2 No. 60601-1- 08 (R2013)
EN 301 489-1 V1.9.2 (2011-09) EN 301 489-3 V1.6.1 (2013-06)
EN 60601-1-2: 2007/AC: 2010 FCC SubPart 15B Class B

Radiance 32" Embedded Display Monitor with ZeroWire Mobile

Standards
IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) EN 60601-1:2006
IEC 60601-1, 3rd Edition (2005)
ANSI/AAMI ES60601- 1:2005+A2 CAN/CSA-C22.2 No. 60601-1-08
EN 301 489-1 V1.9.2 (2011-09) EN 301 489-3 V1.6.1 (2013-06)
EN 60601-1-2: 2007/AC: 2010 FCC SubPart 15 B Class B

O. Summary Changes

The ZeroWire Mobile is an accessory to K151609: ZeroWire Duo Wireless HD Video Transfer System G2/ ZeroWire G2 Duo and K161228: Radiance Ultra Embedded. As an accessory, ZeroWire Mobile did not require any technology or labeling changes to K151609 or K161228 to be compatible.

P. Substantial Equivalency:

The ZeroWire Mobile is substantially equivalent to the safety and effectiveness of K151609: ZeroWire Duo

Wireless HD Video Transfer System G2/ ZeroWire G2 Duo and K161228: Radiance Ultra Embedded as proven in the safety, performance, and verification reports sited in Section N: Performance.

Q. Conclusion:

Based upon the safety, performance, and verification reports, ZeroWire Mobile accessory stand demonstrates safety and effectiveness that is equivalent to the predicate devices: K151609, ZeroWire Duo Wireless HD Video Transfer System G2/ ZeroWire G2 Duo and K161228, Radiance Ultra Embedded.