NDS
SURGICAL · IMAGING

K100195

APR 21 2010

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
C. Date of Preparation:	November 2, 2009 April 15, 2010 revision
D. Contact Information:	Tel: 408-776-0085 Fax: 408-776-9878
E. Classification:	Endoscope and Accessories
F. Common Name:	UWB Wireless Device
G. Proprietary Name:	ZeroWire Duo Wireless HD Video Transfer System
H. Classification Number:	21 CFR 876.1500
I. Product Code:	GCJ
J. Substantial Equivalence:	Stryker Vision Elect Wireless High Definition Television (Stryker VE VHDTV) / K081995 Both the Stryker device and the NDS device contain a wireless, radio frequency transmitter that receives a digital video signal from a surgical camera. Both systems incorporate a wireless, radio frequency receiver that is exclusively linked to but only to the aforementioned transmitter. The wireless receiver of both systems delivers the received video signal to a suitable surgical monitor for use by qualified medical professionals. Both systems conform to non-clinical tests including the medical safety and EMC standards defined by EN 60601-1 and EN 60601-1-2. Both systems require a single transmitter to be linked to an individual receiver. As wireless devices, both systems conform to relevant FCC Part 15 standards. Both systems provide video data security by employing industry-standard data encryption techniques.

The singular difference between the Stryker system and the NDS system is that in the Stryker system the receiver is embedded in the monitor, whereas in the NDS system, the receiver is a separate item which can be electrically connected by means of an appropriate cable to a suitable surgical monitor.

K. Device Description:

The ZeroWire® wireless device is a wireless transmitter and receiver pair which allows delivery of a video signal over a radio frequency link to a video display such as Radiance and EndoVue LCD surgical monitors.

L. Intended Use:

The NDSsi ZeroWire Duo Wireless HD Video Transfer System is a paired transmitter and receiver, intended for delivery of video signals over a radio-frequency link to a video display during endoscopic and general surgical procedures. The ZeroWire wireless device is a non-sterile reusable device not intended for use in the sterile field. It is intended for use by qualified physicians having complete knowledge of these surgical procedures.

M. Technological Characteristics:

The ZeroWire Duo wireless device is a wireless video transfer solution for minimally invasive surgery and interventional procedures. It delivers full high-definition video with less than 1 frame latency. By utilizing the reserved UWB frequency spectrum, ZeroWire provides a wireless video link that is resistant to interference from other devices. ZeroWire improves clinical efficiency and safety in the OR by eliminating the need for video cables – their cleaning, frequent replacement, and potential to be a tripping hazard. The proprietary memory-enabled pairing system makes installation quick and easy.

N. Clinical information:

Clinical data is not needed for this type of wireless device 510(k) submission. However, this submission includes surgical-setting test results to demonstrate the equivalence of the ZeroWire device to the predicate Stryker device.

O. Conclusion:

Based on non-clinical tests as well as surgical-setting tests, the ZeroWire wireless device provides performance, safety, and effectiveness that is equivalent to the predicate Stryker Vision Elect Wireless High Definition Television (Stryker VE VHDTV) / K081995.

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

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NDS Surgical Imaging
% TUV Rheinland of North America, Inc.
Tamas Borsai
Manager, Medical Division
12 Commerce Road
Newton, Connecticut 06470

Re: K100195
Trade/Device Name: ZeroWire Duo Wireless HD Video Transfer System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 02, 2010
Received: April 06, 2010

Dear Tamas Borsai:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510 (k) Number (if Known): _____

Device Name: ZeroWire Duo Wireless HD Video Transfer System

Indications for Use:

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Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIE LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100195