Section 5: 510(k) Summary

Device Information:

Category	Comments
Sponsor:	Company: Foreseeson Custom Display Address: 2210 E. Winston Road Anaheim, CA 92806 Phone: (714) 300-0540 Fax: (714) 300-0546
Correspondent Contact Information:	Daniel Tomlinson Foreseeson Phone: (714) 300-0540 Fax: (714) 300-0546
Device Common Name:	Endoscope and accessories.
Device Classification Number:	21 CFR 876.1500
Device Classification & Product Code:	Class II, GCJ
Device Proprietary Name:	WIS1000

Predicate Device Information:

Predicate Device:	Stryker Vision Elect Wireless High Definition Television (Stryker VE WHDTV)
Predicate Device Manufacturer:	Stryker
Predicate Device Common Name:	Endoscope and accessories.
Predicate Device Premarket Notification #	K081995
Predicate Device Classification:	21 CFR 876.1500
Predicate Device Classification & Product Code:	Class II, GCJ

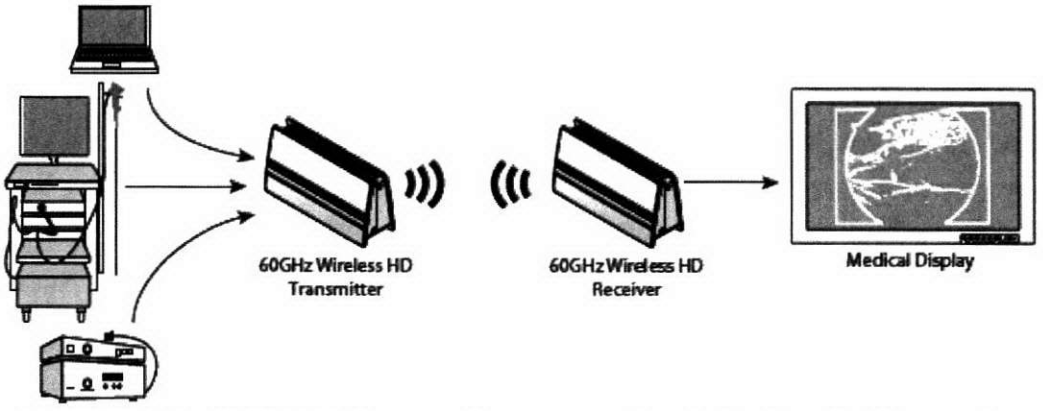
Predicate Device:	ZeroWire Duo Wireless HD Video Transfer System
Predicate Device Manufacturer:	NDSsi
Predicate Device Common Name:	Endoscope and accessories.
Predicate Device Premarket Notification #	K100195
Predicate Device Classification:	21 CFR 876.1500
Predicate Device Classification & Product Code:	Class II, GCJ

b. Date Summary Prepared

24 May 2012

c. Description of Device

The WIS1000 System is a wireless transmitter and receiver pair which allows delivery of High Definition (HD) video from a wide range of video sources common in a hospital environment to a secondary video display.



Typical layout of the WIS1000 System: Sources are hardwired to the Transmitter, the secondary display is hardwired to the Receiver.

Up to six pairs of WIS1000 Transmitters and Receivers can be paired together in a single room.

d. Indications for Use

The Foreseeson Custom Display's WIS1000 transmitter and receiver wirelessly transmit (60GHz) high quality audio and video (up to 1080p/60Hz) to displays during endoscopic and surgical procedures including arthroscopy (orthopedic surgery), laparoscopy (general and gynecological surgery), thorascopy, endoscopy (general, gastroenterological and ENT surgery) and general surgery. The WIS1000 wireless components are non-sterile reusable devices not intended for use in the sterile field.

e. Comparison to Predicate Device

The Foreseeson Custom Display WIS1000 is substantially equivalent in Intended Use, Indications for Use and technology as the predicate Stryker Vision Elect Wireless High Definition Television (K081995) and the NDSsi ZeroWire Duo Wireless HD Video Transfer System (K100195).

All of the device are combinations of wireless paired transmitters and receivers, intended for delivery of video signals over a radio-frequency link to a video display during endoscopic and general surgical procedures. They are all intended to supply images from primary displays to secondary monitors.

All of these wireless devices are reusable and non-sterile. They are not intended for use in the sterile field.

The testing described below demonstrates that the differences in the devices do not raise any unresolved issues of safety or efficacy.

Foreseeson concludes that the devices are substantially equivalent.

f. Summary of Supporting Data

Bench testing has demonstrated that the device is in compliance with IEC 60601-1, IEC 60601-1-2, FCC 47 CFR Part 15, the expectations of the medical community and the product labeling.

Additional compatibility testing was performed to verify that wireless capabilities such as functions, coexistence, quality of service, and security met essential performances.

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

MAY 30 2012

Foreseeson Custom Displays, Inc.
Mr. Daniel Tomlinson
Director, Sales/Marketing /Engineering
2210 E. Winston Road
Anaheim, California 92806

Re: K112621
Trade/Device Name: WIS1000
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: May 03, 2012
Received: May 07, 2012

Dear Mr. Tomlinson:

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,

For Deputy Director

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

Enclosure

Section 4: Indications for Use Statement

510(k) Number (if known): K112621

Device Name: Foreseeson Custom Display WIS1000

Indications For Use:

The Foreseeson Custom Display's WIS1000 transmitter and receiver wirelessly transmit (60GHz) high quality audio and video (up to 1080p/60Hz) to displays during endoscopic and surgical procedures including arthroscopy (orthopedic surgery), laparoscopy (general and gynecological surgery), thorascopy, endoscopy (general, gastroenterological and ENT surgery) and general surgery. The WIS1000 wireless components are non-sterile reusable devices not intended for use in the sterile field.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS 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 K112621