



Food and Drug Administration
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June 8, 2016

Sony Electronics Inc.
Mr. Amarjit Jowandha
Head, Global Quality Assurance, Regulatory Affairs
and Compliance
1 Sony Drive
Park Ridge, New Jersey 07656

Re: K161122
Trade/Device Name: Sony IP Converter NU-IP40S
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 18, 2016
Received: April 21, 2016

Dear Mr. Jowandha:

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 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

4.0 Indications for Use

Sony Electronics Inc.
IP Converter
NU-IP40S

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K161122

Device Name

Sony IP Converter NU-IP40S

Indications for Use (Describe)

The Sony IP Converter's (IPC) intended use is to distribute patient images acquired from modalities within a hospital or clinical environment in almost real-time.

The IPC can send audio visual signals and medical images to various commercially available products such as displays or recording devices commonly used in a medical procedure room or operating room.

The IPC allows for the switching of images easily among devices connected to an IPC in the operating room or throughout a healthcare campus.

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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5.0 510(k) Summary

Sony Electronics Inc.
IP Converter
NU-IP40S

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

510(k) Number: _____

5.1 Applicant Information

Date Prepared:	April 18, 2016
Company Name and Address:	Sony Electronics, Inc. Sony Medical Systems Division 1 Sony Drive, Mail Stop 2E2 Park Ridge, NJ 07656-8004 United States of America
Contact Person:	Mr. Amarjit "Andy" Jowandha Head, Global Quality Assurance, Regulatory Affairs & Compliance Phone: +1 (201) 930-6078 FAX: +1 (201) 930-6307 Email: Amarjit.Jowandha@am.sony.com

5.2 Device Information

Device Type:	IP Converter
Regulation Description:	Endoscope and Accessories
Review Panel:	General & Plastic Surgery
Regulation Number:	21 CFR 876.1500
Product Code:	GCJ
Device Class:	II
Device Name:	NU-IP40S

5.3 Predicate Devices

The legally marketed devices to which substantial equivalence is being claimed are:

510(k) Number:	K122167	K070556	K033132
Applicant:	BARCO NV	BrainLAB AG	Stryker Communications Corp.
Device Name:	NEXXIS OR	BrainSUITE NET	Switchpoint Infinity Control System
Regulation Number:	21 CFR 870.2450	21 CFR 876.1500 and 21 CFR 882.4560	21 CFR 876.1500
Product Code:	DXJ	GCJ and HAW	GCJ
Device Class:	II	II	II

5.0 510(k) Summary

Sony Electronics Inc.
IP Converter
NU-IP40S

5.4 Device Description

The Sony IP Converter NU-IP40S is intended to transmit 4K or HD video and audio signals from endoscope system or other modalities equipped with 3G/HD-SDI video output via a high-speed optical fiber network with minimal delay.

Connecting multiple IP Converters via a network switch can construct a network video transmission system for medical procedures.

5.5 Intended Use/Indications for Use

The Sony IP Converter's (IPC) intended use is to distribute patient images acquired from modalities within a hospital or clinical environment in almost real time.

The IPC can send audio visual signals and medical images to various commercially available products such as displays or recording devices commonly used in a medical procedure room or operating room.

The IPC allows for the switching of images easily among devices connected to an IPC in the operating room or throughout a healthcare campus.

5.6 Technological Characteristics

The subject device compares to the legally marketed devices as follows:

Device	Subject Device	Predicate Devices		
	IP Converter NU-IP40S	NEXXIS OR (K122167)	BrainSUITE NET (K070556)	Switchpoint Infinity (K033132)
Classification Regulation	21 CFR 876.1500	21 CFR 870.2450	21 CFR 876.1500 21 CFR 882.4560	21 CFR 876.1500
Product Codes	GCJ	DXJ	GCJ HAW	GCJ
Class	II	II	II	II
Intended Use/Indications for Use	<p>The Sony IP Converter's (IPC) intended use is to distribute patient images acquired from modalities within a hospital or clinical environment in almost real-time.</p> <p>The IPC can send audio visual signals and medical images to various commercially available products such as displays or recording devices commonly used in a medical procedure room or operating room.</p>	<p>The Barco Nexxis OR system is designed to allow transfer, selection and distribution of A/V signals and medical images from various commercially available instruments that are commonly used in a medical procedure laboratory or operating room.</p> <p>The Barco Nexxis OR system is also designed for transfer, selection and distribution of human interface signals and control</p>	<p>BrainSUITE NET from BrainLAB is a platform for the integration of devices and for the distribution of video signals and multimedia content. It is intended to be used for communication between compatible BrainLAB devices.</p> <p>It provides centralized access for managing video data, medical images and patient data.</p> <p>BrainSUITE NET can be used in the</p>	<p>The Switchpoint Infinity Control System is a medical device that is designed to allow direct control of the state, selection, and settings of room equipment, and audio/video equipment and indirect control through the Stryker Endoscopy Sidne System of the state, selection, and settings of surgical equipment in the operating room. The Switchpoint Infinity Control System is also an integrated voice, video, and</p>

5.0 510(k) Summary

Sony Electronics Inc.
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Device	Subject Device	Predicate Devices		
	IP Converter NU-IP40S	NEXXIS OR (K122167)	BrainSUITE NET (K070556)	Switchpoint Infinity (K033132)
	<p>The IPC allows for the switching of images easily among devices connected to an IPC in the operating room or throughout a healthcare campus.</p>	<p>signals of non-medical room equipment.</p> <p>The Barco Nexxis OR system allows control and selection of these signals from a central point.</p> <p>The Barco Nexxis OR system is not intended to be used for remote or robotically-assisted surgery.</p> <p>The Barco Nexxis OR system is not intended to be used in the vicinity of MRI or other devices that use strong magnetic fields.</p>	<p>operating theater for various surgical procedures involving video processing, image recording, patient data viewing and software application control.</p>	<p>data router and teleconferencing interface for the operating room. The intent of the Switchpoint Infinity Control System is to allow operating room personnel a center point for controlling all equipment and communication in surgery.</p> <p>The Stryker Switchpoint Infinity Control System is indicated for use with the Stryker Endoscopy Sidne System [510(k) # K022393] and Sidne compatible endoscopic and general surgery devices. The users of Switchpoint Infinity Control System are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, urologists, radiologists, and any other surgeon whom requires the use of voice, video, or control in the operating room or a teleconferencing interface.</p>
Product Configuration	<p>Consists of:</p> <ul style="list-style-type: none"> • Internet protocol converter (mandatory) <ul style="list-style-type: none"> ○ NU-IP40S • Network System Manager 	<p>Consists of:</p> <ul style="list-style-type: none"> • Nexxis MNA encoders and decoders (mandatory) <ul style="list-style-type: none"> ○ MNA-120 ENC ○ MNA-120 DEC 	<p>Consists of:</p> <ul style="list-style-type: none"> • Touchscreen interface • A/V displays <ul style="list-style-type: none"> ○ Not provided ○ Exist inside and outside 	<p>Consists of:</p> <ul style="list-style-type: none"> • Media router • Control system • Touchscreen interface • A/V displays <ul style="list-style-type: none"> ○ Not provided ○ Exist inside

5.0 510(k) Summary

Sony Electronics Inc.
IP Converter
NU-IP40S

Device	Subject Device	Predicate Devices		
	IP Converter NU-IP40S	NEXXIS OR (K122167)	BrainSUITE NET (K070556)	Switchpoint Infinity (K033132)
	<ul style="list-style-type: none"> (optional) <ul style="list-style-type: none"> ○ NU-NM10B • A/V displays <ul style="list-style-type: none"> ○ Not provided ○ Exist inside and outside operating room 	<ul style="list-style-type: none"> • Network management software (mandatory) <ul style="list-style-type: none"> ○ Nexxis OR Management Suite • Nexxis Network Switch <ul style="list-style-type: none"> ○ Extreme network switch (optional) • A/V displays <ul style="list-style-type: none"> ○ Not provided ○ Exist inside and outside operating room 	operating room	and outside operating room
Supported Signal Formats	<ul style="list-style-type: none"> • HD-SDI • 3G-SDI • Quad Link 3G-SDI • 3D 	<ul style="list-style-type: none"> • DVI-D • SDI • DP 	Wide range per K070556 510(k) Summary	<ul style="list-style-type: none"> • S-Video • Composite • RGBHV • 3G-SDI • HD-SDI • DVI
Supported Video Resolution	<ul style="list-style-type: none"> • 1920x1080 • 3840x2160 • 4096x2160 	<ul style="list-style-type: none"> • 1920x1200 maximum 	Unknown	<ul style="list-style-type: none"> • 1920x1080 • 1920x1200
Power Specifications	<ul style="list-style-type: none"> • +24 V DC, 1 A, 24 W 	<ul style="list-style-type: none"> • 100-120, 200-240 VAC, 50/60Hz, 30 W max 	Unknown	<ul style="list-style-type: none"> • 100-240 VAC, 50/60 Hz, 570 VA (Media router) • 120-240 VAC, 50/60 Hz, 400 VA (Control system)
Physical Specifications	<ul style="list-style-type: none"> • Ordinary protection against harmful ingress of water • Approx. 0.7 kg (1 lb. 8 oz.) • VESA 100 compatible with adaptation plate 	<ul style="list-style-type: none"> • IPX0 • 750 g • VESA 100 compatible with adaptation plate 	Unknown	<ul style="list-style-type: none"> • 34 kg, 24" H x 20.6" W x 17" D (Media router) • 4.08 kg, 2.6" H x 12.6" W x 17" D (Control system)
Software User Interface	Optional accessory Network System Manager (NSM) software allows control of multiple IP converters and enables video	Network management software (mandatory) provides software control interface for layout, status and	Single touchscreen interface enables full control of video signals allowing manipulation of how/where information is	Control system is an integrated voice, video, and data router and teleconferencing interface for the operating room

5.0 510(k) Summary

Sony Electronics Inc.
*IP Converter
 NU-IP40S*

Device	Subject Device	Predicate Devices		
	IP Converter NU-IP40S	NEXXIS OR (K122167)	BrainSUITE NET (K070556)	Switchpoint Infinity (K033132)
	switching from a server computer connected to the same network	diagnosis, LED indicators for power supplies	displayed, such as monitors in the operating room or in remote rooms	
Distributes Audio / Video Signals Inside the Operating Room?	Yes	Yes	Yes	Yes
Distributes Audio / Video Signals Outside the Operating Room?	Yes	Yes	Yes	No
Enables Centralized Management of Audio / Video Signals?	Yes	Yes	Yes	Yes
Performance Standards	<ul style="list-style-type: none"> • ANSI/AAMI ES60601-1:2005 • IEC 60601-1-2:2007 • IEC 62304:2006 • ISO 14971:2007 	<ul style="list-style-type: none"> • IEC 60601-1 • IEC 60601-1-2:2001 • ISO 14971 	<ul style="list-style-type: none"> • IEC 60601-1-1 • IEC 60601-1-2 	<ul style="list-style-type: none"> • UL 60601-1 • EN 60601-1-2

5.7 Non-Clinical Performance Data

The subject devices demonstrate conformance with the following recognized standards:

- ANSI/AAMI ES60601-1
- IEC 60601-1-2
- IEC 62304
- ISO 14971

5.8 Clinical Performance Data

No clinical study is included in this submission.

5.9 Conclusions

Based on the above information and all data provided in this submission, the comparison of intended uses, technological characteristics, and non-clinical performance testing demonstrates that the subject devices are substantially equivalent to the predicate device identified in this submission.