January 9, 2020

Sony Electronics Inc.
% Tomomichi Iwasaka
Senior Manager of Regulatory Affairs section
Sony Corporation, Atsugi Technology Center
4-14-1 Asahi-Cho
Atsugi-Shi, Kanagawa, JAPAN 243-0014

Re: K191678
Trade/Device Name: Sony IP Converter NU-IP3T, Sony IP Converter NU-IP3R
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 17, 2019
Received: June 24, 2019

Dear Tomomichi Iwasaka:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191678

Device Name
Sony IP Converter NU-IP3T
Sony IP Converter NU-IP3R

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 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Date of the summary prepared: June 17, 2019

510(k) Number: K191678

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.

1 Applicant Information

Company Name and Address:	Sony Electronics Inc., 115 West Century Road Suite 250 Paramus, NJ 07652 Phone Number: (201)358-4082 FAX Number: (201)930-6307

2 Application Correspondent / Contact

Company Name and Address:	Sony Corporation, Atsugi Technology Center 4-14-1 Asahi-Cho Atsugi-Shi, Kanagawa, JAPAN 243-0014
Contact:	Phone Number: +81-50-3141-0325 FAX Number: +81-50-3141-2453 Contact E-mail Address: T.Iwasaka@sony.com Contact Name: Tomomichi Iwasaka

3 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:	Sony IP Converter NU-IP3T Sony IP Converter NU-IP3R

4 Predicate Device(s)

The legally marketed device to which substantial equivalence is being claimed is:

510(k) Number:	K161122
Device Name:	Sony IP Converter NU-IP40S
Applicant:	SONY ELECTRONICS INC. 1 SONY DRIVE park ridge, NJ 07656
Regulation Number:	21 CFR 876.1500
Product Code:	GCJ
Device Class:	II

5 Device Description

The NU-IP3T/NU-IP3R IP converters are devices for the transmission/reception of 4K or HD images over a network with low latency from devices equipped with 3G-SDI, HDMI, Display Port, or DVI image outputs.
Connecting multiple IP converters via a network switch allows you to construct a network video transmission system for medical procedures.

6 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 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.

7 Technological Characteristics

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

Device	**Subject Device** **Sony IP Converter NU-IP3T** **Sony IP ConveterNU-IP3R**	**Predicate Device(s)** **Sony IP Converter NU-IP40S**
Product Configuration	Consists of: • Internet protocol converter (mandatory) o NU-IP3T (for Transmitter) o NU-IP3R (for Receiver) • Network System Manager (optional software) o NU-NM30E • A/V displays o Not provided o Exist inside and outside operating room	Consists of: • Internet protocol converter (mandatory) o NU-IP40S (for Transmitter and Receiver) • Network System Manager (optional software) o NU-NM10B • A/V displays o Not provided o Exist inside and outside operating room

Device	Subject Device	Predicate Device(s)
	Sony IP Converter NU-IP3T **Sony IP ConveterNU-IP3R**	**Sony IP Converter NU-IP40S**
Supported Signal Formats	• HD-SDI • 3G-SDI • Quad Link 3G-SDI • Display Port 1.2 • HDMI 2.0 • DVI • Analog RGB • Component • Composite	• HD-SDI • 3G-SDI • Quad Link 3G-SDI • 3D
Supported Video Resolution	• 640x480 • 720x480 • 720x576 • 800x600 • 1024x768 • 1280x720 • 1280x768 • 1280x1024 • 1366x768 • 1920x1080 • 3840x2160 • 4096x2160	• 1920x1080 • 3840x2160 • 4096x2160
Power Specifications	• +24 V DC, 2 A, 38W (NU-IP3T) • +24 V DC, 2 A, 42W (NU-IP3R)	• +24 V DC, 1 A, 24W
Physical Specifications	• Ordinary protection against harmful ingress of water • Approx. 1.0 kg (2 lb 3.2 oz) (NU-IP3T) • Approx. 1.2 kg (2 lb 10 oz) (NU-IP3R) • Adaptation plate (Back of the monitor)	• Ordinary protection against harmful ingress of water • Approx. 0.7 kg (1 lb. 8 oz.) • VESA 100 compatible with adaptation plate
Software User Interface	Optional accessory Network System Manager (NSM) software allows control of multiple IP converters and enables video switching from a server computer connected to the same network	Optional accessory Network System Manager (NSM) software allows control of multiple IP converters and enables video switching from a server computer connected to the same network
Software Main Function	• IP transmission of video signals • Auto input signal detection • Video signal codec • Thumbnail generation • IP reception of video signals • Video output • Firmware update • PiP/PaP • Still image create • Still image display • Direct video output	• IP transmission of video signals • Auto input signal detection • Video signal codec • Thumbnail generation • IP reception of video signals • Video output • Firmware update • Switching of channels used for video signal transmission • Redundant network transmission function • RS232 serial control
Distributes Audio / Video Signals Inside the Operating Room?	Yes Video only	Yes
Distributes Audio / Video Signals Outside the Operating Room?	Yes Video only	Yes

Device	Subject Device	Predicate Device(s)
	Sony IP Converter NU-IP3T **Sony IP ConveterNU-IP3R**	**Sony IP Converter NU-IP40S**
Enables Centralized Management of Audio / Video Signals?	Yes Video only	Yes
Performance Standards	• ANSI/AAMI ES60601-1:2005(R), 2012 (IEC:3.1) • IEC 60601-1-2:2014 • IEC 62304:2006/A1:2015 • ISO 14971:2007	• ANSI/AAMI ES60601-1:2005 • IEC 60601-1-2:2007 • IEC 62304:2006 • ISO 14971:2007

8 Non-Clinical Performance Data

The subject devices demonstrate conformance with the following recognized standards:

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

9 Clinical Performance Data

No clinical study is included in this submission.

10 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.