DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

August 16, 2017

INTEGRAL PROCESS SAS
Virginie Grondin
Quality & Regulatory Affairs Manager
12 Rue Des Cayennes
Po Box B.P. 20310
Conflans Sainte Honorine, 78703 Fr

Re: K162768
Trade/Device Name: Integral-Process Medical Patient and Leadwire systems: ECG trunk cables, ECG leadwires, SpO^2 sensors interface cables and IBP transducers interface cables
Regulation Number: 21 CFR 870.2900
Regulation Name: Cable, Transducer and Electrode, Patient, (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: July 7, 2017
Received: July 13, 2017

Dear Virginie Grondin:

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,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K162768

Device Name

Integral-Process Medical Patient Cable and Leadwire Systems: systems: ECG trunk cables, ECG leadwires, SpO^2 sensors interface cables and IBP

Indications for Use *(Describe)*

Integral-Process Medical Patient Cable and Leadwire Systems are intended to be used with various electrocardiograph recorders/monitors for both diagnostic and monitoring purposes such as ECG, EKG, SpO2 and Blood Pressure equipment. They are solely intended to be used between the electrode in contact with the patient's skin and the recording/monitoring device. This cabling facilitates the conduction of signals between the patient and the monitoring device. Integral-Process Medical Patient Cable and Leadwire Systems are limited by the Indications for Use of the connected recording/monitoring device.

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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510(k) Summary

Administrative:

Submitter: INTEGRAL PROCESS SAS
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Establishment Registration Number: 3004762958

Date of preparation: July 21, 2016

I. Device Name:

Classification Name: Cable, transducer and electrode, patient, (including connector)
Regulation description Patient transducer and electrode cable (including connector)
Common/Usual Name: Patient cables and Leadwires
Trade Name: Integral-Process Medical Patient and Leadwire systems: ECG trunk cables, ECG leadwires, SpO^2 sensors interface cables and IBP transducers interface cables.

Classification: Class II
Registration #: 870.2900
Product Code: DSA

II. Predicate Devices:

We have to consider the legally marketed closest existing devices to the Integral Process Medical Patient Cable and Leadwire Systems submitted devices and we will separate the following aspects:
Functionality (indication); Patient Usage; Positioning of the EKG/ECG Leadwires; Design and Shape; Cable Length; Materials; Sterility; Mechanical and Electrical Performance and Safety.

List of Predicate Devices:

Substantial Equivalence	K #	Manufacturer / Current marketer	Device I/D
EKG/ECG, SpO2, IBP Cables	**K120010**	Shenzhen Med-link ElectronicsTech Co., Ltd. Building2, HuaFu Ind. Park, HuaWang Road, LongHua, BaoAn, District 518109 Shenzhen City, P.R.China	Cable/ lead-wire (ECG, EKG, SpO2 and Invasive Blood Pressure) (*)
EKG/ECG, SpO2, IBP Cables	**K992524**	Advantage Medical Cables, Inc. 10630 Wiles Road Coral Springs, FL 33076 USA	Patient Monitoring Cables for ECG, EKG, Sp02 and Blood Pressure Monitors (*)
EKG/ECG, SpO2, IBP Cables	**K082959**	Unimed Medical Supplies, Inc. No.37, Yanshan Road, Shekou Shenzhen, 518067 China	Patient monitoring Cables for ECG, EKG,Spo2 and Blood Pressure Monitors (*)
			(*) Multiple References See detailed catalogues and tables Attachment I & III

Comparison of cable / lead-wires has the same or similar technological characteristics as the Predicates:

Comparison item	Integral-Process Medical Patient Cable and Leadwire systems	Shenzhen Med-link	Advantage medical	Unimed Medical
K#	t.b.d.	K120010	K992524	K082959
Indication	Integral-Process Medical Patient Cable and Leadwire Systems are intended to be used with various electrocardiograph recorders/monitors for both diagnostic and monitoring purposes such as ECG, EKG, SpO2 and Blood Pressure equipment. They are solely intended to be used between the electrode in contact with the patient's skin and the recording/monitoring device. This cabling facilitates the conduction of signals between the patient and the monitoring device. Integral-Process Medical Patient Cable and Leadwire Systems are limited by the Indications for Use of the connected recording/monitoring device.	Shenzhen Med-link Cable / lead-wire are intended to be used with ECG, EKG, Sp02 and Invasive Blood Pressure monitoring devices. The Cable / lead-wire are used to connect electrodes, catheters, and/or sensors placed at appropriate sites on the patient to a monitoring device for general monitoring andfor diagnostic evaluation by heath care professional.	These patient cables and leadwires are intended to be used with ECG, EKG, Sp02 and Blood Pressure monitoring devices.	The Unimed patient cables and lead wires are intended to be used with ECG, EKG, sp02 and BP monitoring devices. The patient cables and lead wire are used to connect electrodes, catheters, and / or sensors placed at appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by heath care professional.
Patient Usage	Reusable	Reusable	Reusable	Reusable
Anatomical Sites	The leadwire is connected to the ECG or EKG electrodes placed at standard specified locations on the patient limbs and/or chest.	The ECG and EKG cable are attached to sensors placed at standard specified locations on the chest wall.	The ECG and EKG cable are attached to sensors placed at standard specified locations on the chest wall.	The ECG and EKG cable are attached to sensors placed at standard specified locations on the chest wall.
Design	ECG and EKG cables / leadwires have various designed connectors (monitor, trunk yokes, lead wire, electrode grabber, snap and banana)	ECG and EKG Cables with various connectors (monitor, trunk / lead wire, electrode grabber & snapper)	ECG and EKG Cables with various connectors (monitor, trunk / lead wire, electrode grabber & snapper)	ECG and EKG Cables with various connectors (monitor, trunk / lead wire, electrode grabber & snapper)
	Integral Process invasive blood pressure cable has various connectors (Yoke type: on the transducer side, instrument connector on the other side.	Invasive Blood Pressure cables with various connectors (Yoke type: Utah 4pin, Instrument connector: Spacelabs 6 Pin etc.)	Invasive Blood Pressure cables with various connectors (Yoke type: Utah 4pin, Instrument connector: Spacelabs 6 Pin etc.)	Invasive Blood Pressure cables with various connectors (Yoke type: Utah 4pin, Instrument connector: Spacelabs 6 Pin etc.)

Comparison item	Integral-Process Medical Patient Cable and Leadwire systems	Shenzhen Med-link	Advantage medical	Unimed Medical
	Integral Process SpO² cable has various connectors to connect the OEM instrument connector of SpO² monitor and SpO² probe. (DB9, Din 8Pin, Philips, etc.)	SpO2 adapter cables with various connectors for connect for the OEM Instrument connector of Sp02 monitor and Sp02 probe. (DB9, Din 8Pin and Philips round 8Pin etc.)	SpO2 adapter cables with various connectors for connect for the OEM Instrument connector of Sp02 monitor and Sp02 probe. (DB9, Din 8Pin and Philips round 8Pin etc.)	SpO2 adapter cables with various connectors for connect for the OEM Instrument connector of Sp02 monitor and Sp02 probe. (DB9, Din 8Pin and Philips round 8Pin etc.)
	Integral Process Medical Patient Cable and Leadwire Systems cover a much larger range of devices combining on their both sides all type of connectors than the selected predicate devices, without altering either intended use or the transfer signal functionality.			
Cable Lengths	Various specified standard lengths	Various specified standard lengths	Various specified standard lengths	Various specified standard lengths
Wire material	Shielded & Unshielded Copper; medical grade TPU cable jacket with medical grade PA overmolded connectors with integral strain relief.	Shielded & Unshielded Copper with PVC or TPU Jacket	Shielded & Unshielded Copper with PVC Jacket	Shielded & Unshielded Copper with PVC Jacket
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Connector Retention Force	ANSI / AAMI EC53A:1998 (R)2001	ANSI / AAMI EC53:1995 (R)2001	ANSI / AAMI EC53:1995	ANSI / AAMI EC53A:1998 (R)2001 EC53A-1998 (Amendment)
Electrical Performance and Safety	ANSI / AAMI EC53:1995 (R)2001	ANSI / AAMI EC53:1995 (R)2001 and IEC 60601-1:1998; Am1; A2:1995	ANSI / AAMI EC53:1995 and IEC 60601-1:1998; Am1; A2:1995	ANSI / AAMI EC53A:1998 (R)2001 and IEC 60601-1:1998; Am1; A2:1995

Representative samples of INTEGRAL PROCESS range of patient cables:

Although the total amount of the different cables presented in this submission is around 1260 part numbers we need a limited quantity of samples to have a good representation of the total range.

If we consider that cables have two ends and often an intermediate yoke we have defined 4 categories of connectors:

1) Monitor side connectors
All the INTEGRAL PROCESS cables connectors on monitor side can be represented with 8 types of connectors (From MC1 to MC8)

2) Intermediate connectors (Trunk cable yoke, IPB or SpO² sensor side connector)
All connectors can be represented with 8 different types of connectors (From YC1 to YC8).

3) Yoke side leadwires connectors
Four different types of connectors represent all the different leadwires connectors to the trunk cable yoke (From LY1 to LY4).

4) Patient side leadwires connexions
Four different types of connectors [Banana, Snap, Clip (with metal conductor) and Carbon Clip]. Those ends are on the patient side of the one piece ECG cables and of the detachable leadwires.

Integral-Process Cable P/N	Description (Connected Medical Equipment)	**Predicate Reference**	**Predicate Name & K#**	**Monitor side connector**	**Middle connexion**	**Connector between Leadwire and Trunk cable yoke**	**Patient Side Connector**
72279-US	NIHON KOHDEN CARDIOFAX OLD GENERATION 5151-5303	CB-72353P	Advantage K992524	MC1	YC4		Banana
71710-US	GE-MAC 1100 – 1200 MAC 400-600-800	CB-721001R/1	//	MC2	YC2		
72512-US	MEDTRONIC PHYSIOCONTROLLIFEPAK 12	CB-721007R /1	//	MC3	YC4		Clip
90797IP	MINDRAY DATASCOPE BENEVIEW T5 - T8 IPM9800 D6	S0125CO-L**	Shenzen K120010	MC4	YC5		
72240-US	NIHON KOHDEN BSM 2103-4103K	CB-713600	Advantage K992524	MC5	YC1		
88769	DRAEGER SIEMENS	CB-91018	//	MC7	YC7		
87550	GE EAGLE TRAM	BC-MC-MX1*	Unimed K082959	MC6	YC6		
IPC71040	BARD ELECTROPHYSIOLOGY UNIT	CB-721020R/1	Advantage K992524	MC8	YC3		
90766IP	PHILIPS M3 - M4 - VSM MMS MP2 à MP70	CB-A400-1006VM	//	MC4	YC8		
71796-US	PHILIPS ECG100/200 Serie	CB-721014R/1	//	MC2	YC3		Snap
70626NGJ3-US	3 Leadwires for IP Trunk cables	LW-3090R24/3A	//			LY1	Snap
70686NG-US	Single IP Radiolucent leadwire	LW-2300051/XA	//			LY3 carbon	Clip carbon
70822	3 Leadwires for IP paediatric trunk cable	LW-2090029/3A	//			LY2	Snap
70683HPJ3-US	3 Leadwires for PHILIPS Acquisition Box: M1663A – M1668A – M1669A – M1949A	LW-2090S51/3A	//			LY3	Clip
70646WAJ10-US	3 Leadwires WELCH ALLYN ACQUISITION BOX: CP100 – CP200	EG040S5A**	Shenzen K120010			LY4	Clip

Substantial Equivalence by Selected (Sampling) References:

Substantial Equivalence	**Integral Process Device P/N**	**Predicate Device P/N**	**K #**	**Manufacturer / Current marketer**
ECG one piece and trunk cables	72512-US 72240-US IPC71040	CB-721007R /1 CB-713600 CB-721020R/1	K992524	Advantage Medical Cables Inc. (AMC)

Substantial Equivalence	Integral Process Device P/N	Predicate Device P/N	K #	Manufacturer / Current marketer
ECG leadwires	70626NGJ3-US 70686NG-US 70822 70683HPJ3-US	LW-3090R24/3A LW-2300051/XA LW-2090029/3A LW-2090S51/3A	K992524	Advantage Medical Cables Inc. (AMC)
ECG leadwires (cont)	70646WAJ10-US	EG040S5A	K120010	Shenzhen Med-link Electronics Tech CO., Ltd.
EKG cables and leadwires	72279-US 71710-US 71796-US	CB-72353P CB-721001R/1 CB-721014R/1	K992524	Advantage Medical Cables Inc. (AMC)
SpO² sensor interface cables	90797IP	S0125CO-L	K120010	Shenzhen Med-link Electronics Tech CO., Ltd.
	90766IP	CB-A400-1006VM	K992524	Advantage Medical Cables Inc. (AMC)
IBP transducer interface cables	88769	CB-91018	K992524	Advantage Medical Cables Inc. (AMC)
	87550	BC-MC-MX1	K082959	Unlined Medical supplies Inc

III. **Device Description:**

Integral-Process Medical Patient Cable and Leadwire Systems are electrical cables interfacing and connecting transducers/sensors/electrodes placed on patients, to monitoring/recording/diagnostic devices/equipment. Such equipment is commonly located in hospitals, doctor's offices, emergency vehicles, as well as in home use.

This cabling facilitates the conduction of signals between the patient and the monitoring/recording/diagnostic device.

Original Equipment Manufacturers (OEM) of either sides: e.g. sensors/captors/electrodes and monitoring/recording/diagnostic devices may be identical or different depending on source and period of supplies.

Integral-Process manufactures all type of interfacing transducer and patient cables, as replacement cables and/or as sub-contractor of main brands.

We can divide these Medical Patient Cable and Leadwire systems in 3 categories:

1) Electrocardiograph (EKG/ECG) cables (also sometimes referred to as trunk or lead wires) are replacements for similar cables manufactured by the OEM and other third party after market manufacturers for their respective monitors. The Trunk Cables connect the OEM patient monitor to the patient Lead Wires. The lead wires connect the trunk cable to the skin-mounted ECG electrodes. Additional Trunk Cables have a specific connector for Integral-Process proprietary pre-wired and harnessed electrode systems IP-SET

The most common cable configuration is of a 3, 5 or 10 conductors cable with a metal or plastic connector terminated on one end by crimp or solder method, using various keyway configurations depending on the make and model of the monitor, for connection to the monitoring device, and the 3, 5 or 10 conductors terminated into a connector or yoke assembly either for standard lead wires or for an IP-SET pre wired harness to attach on the other hand.

IP-SET® prewired harnessed electrodes are the object of a separate premarket notification file. (K101685)

Standard lead wires may be permanently attached to the yoke or terminated on one end with a 0.60 diameter pin and over molded with the mating DIN style connector and a snap or pinch type connector on the other hand for connection to the patient electrodes.

2) and 3) SpO2 and IBPT cables are connecting directly patient transducers and sensors to monitoring/recording/diagnostic equipment. The Integral Process manufactures a much larger range of cables combining on their both sides (Equipment, all type of patient connectors) than the selected predicate devices, without altering either intended use or the transfer signal functionality.

Although the total amount of the different cables presented in this submission is around 1260 part numbers we selected a limited quantity of samples to have a good representation of the total range, as shown above (Predicate Device Comparison)

IV Conformance Standards

Standards Applicable to Company

cGMP (21 CFR 820)	QSR - Manufacturing
ISO 13485:2012 / 2003	Quality System for Medical Device Manufacturing

Standards Applicable to Product

21CFR898	PERFORMANCE STANDARD FOR ELECTRODE LEAD WIRES AND PATIENT CABLES
AAMI/ANSI EC53:2013	ECG Cables and Lead Wires
ISO 14971 2007	Medical devices - Application of risk management to medical devices
IEC 60601-1: 1988 +A1 1991 +A2 1995 § -56.3	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance: - Connectors
IEC 60601-1 2005 / 2012	Medical electrical equipment - Part 1: General
IEC 60601-2-25:2011	Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 60601-2-27:2011/AC1:2012	Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
ISO 80601-2-61:2011	Particular requirements for basic safety and essential performance of pulse oximeter equipment
IEC 60601-2-34:2011	Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
IEC 60601-2-49 2011	Particular requirements for the basic safety and essential performance of multi-function patient monitoring equipment
ISO 10993-1	Biological evaluation of medical devices Part 1: Evaluation and testing
ISO 10993-5	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity

ISO 10993-10	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization

V Indications for Use

Integral-Process Medical Patient Cable and Leadwire Systems are intended to be used with various electrocardiograph recorders/monitors for both diagnostic and monitoring purposes such as ECG, EKG, SpO2 and Blood Pressure equipment. They are solely intended to be used between the electrode in contact with the patient's skin and the recording/monitoring device. This cabling facilitates the conduction of signals between the patient and the monitoring device. Integral-Process Medical Patient Cable and Leadwire Systems are limited by the Indications for Use of the connected recording/monitoring device.

VI Comparison of Technological Characteristics

The Reusable Integral-Process Medical Patient Cable and Leadwire Systems are identical in function, and have the same intended use as the legally marketed disposable patient cables and leadwires that are intended to be used with ECG, EKG, Sp02 and Blood Pressure monitoring devices, from Shenzhen Med-link Electronics Tech CO., Ltd. (K120010), Unimed Medical Supplies Inc. (K082959) and Advantage Medical Cables Inc. (AMC) (K992524).

Other effectiveness and safety compliance (electrical safety and biocompatibility of skin-contact components) to required standards and requirements are demonstrated in the market authorization file.

Accordingly Integral-Process concluded that the Integral Process Medical Patient Cable and Leadwire Systems are as safe, as effective for their intended use and perform as well as or better than the legally marketed devices that are intended to be used with ECG, EKG, SpO2 and Blood Pressure monitoring devices.