A.T.S. Applicazione Tecnologie Speciali S.R.L.
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

July 9, 2021

Re: K211542
Trade/Device Name: PRIMO S
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: May 13, 2021
Received: May 19, 2021

Dear Mr. Kamm:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211542

Device Name
PRIMO S

Indications for Use *(Describe)*
Intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. The kit allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.

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.

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510(k) Summary K211542

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Date Prepared: July 2, 2021

1. **Administrative Information**

   Submitter:
   Submission contact person: Eng. Livia PILLITTERI, QMS & Regulatory Affairs Manager

   Identification:
   Trade/Device Name: PRIMO S
   Regulation Number: 21 CFR 892.1680
   Regulation Name: Stationary X-ray System
   Regulatory Class: II
   Product Code: MQB, IZL

   Substantially equivalent device:
   Sedecal SA K130883
   Trade/Device Name: Sedecal Digital Radiographic Upgrade Model SDRU-T
   Regulation Number: 21 CFR 892.1680
   Regulation Name: Stationary X-ray System
   Regulatory Class: II
   Product Code: MQB

   Reference devices:
   See table of compatible digital panels below.

2. **Indications for Use:** Intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. The kit allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.

3. **Device description:** PRIMO S is an image acquisition and processing software application, in radiography mode for Flat Panel detectors. The software is specifically designed for integration with production equipment of the SEDECAL group. The PRIMO S application will be used on different types of Sedecal equipment / systems:
   - mobile units
   - fixed installations.

The PRIMO S VP application provides the following functions:

- User login: the device is usable only by authenticated users
- Management of the operator interface GUIs and setup of the application itself
- The operator interface GUI must reserve a space on the monitor for the Sedecal equipment/system GUI (choice of examination (APR), X-ray generator commands, collimator, stand, etc.)
- Management of patient data through manual entry and reception from the DICOM WORKLIST service
- Management of image processing algorithms for each type of examination
- Management of the automatic advancement procedures of the operations during the study.
- Image acquisition and processing
- Saving in Hard Disk of the acquired images
- Automatic and manual image stitching procedure
- Off-line image editing and optimization using process and graphic functions
- Documentation of images and study data using DICOM services of STORE, PRINT, CDROM, MPPS, RDSR, STORAGE COMMITMENT
- Application configuration setup
- Export and automatic saving of images on external support (USB key)

The application communicates with the Sedecal equipment through software modules (DLL) for:

- The choice of the examination, made by the operator through a GUI defined by Sedecal (APR)
- Send the exposure parameters foreseen by the selected exam (kV, mA, mAs, ms, collimator aperture, stand position, ...)
- Receive the system status parameters and the exposure result

4. **Technological characteristics**: Comparison Table

Comparable Properties	Sedecal SA K130883 Sedecal Digital Radiographic Upgrade Model SDRU-T	PRIMO S	Comparison Results
Indications for use	Intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. The kit allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.	Intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. The kit allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.	SAME
X-ray Generator	Sedecal	Sedecal	SAME
Digital X-Ray Detectors	Toshiba FDX 3543RP, FDX 4343R; (Now called Canon)	Same plus additional panels, see list below.	SAME

Comparable Properties	Sedecal SA K130883 Sedecal Digital Radiographic Upgrade Model SDRU-T	PRIMO S	Comparison Results
Panel Sizes	14 x 17, 17 x 17 Inches	14 x 17, 17 x 17, 10 x 12 Inches	Almost IDENTICAL. 10 x 12 Inches added for imaging extremities
Operating System	Windows 7	Windows 10	Updated OS is required.
Power Source	AC Line	AC Line	SAME.
Standards	Same as below	See below	SAME

Compatible Flat Panel Display (FPD) List

FPD Trade mark	FPD model	510(K) File
Canon / Toshiba	AR-A4343W (same as CXDI-401 C Wireless)	K171270
	AR-A3543W (same as CDXI-701C Wireless)	K170332
	FDXA4343R-HD	K162687
	FDX2530RPW	K162687
iRay	Mars1717V-VSI	K201043
	Mars1417V-TSI	K201004
	Venu1717	K123644
	Mars 1417X	K210316
	Mars 1717X	K210314

5. Non clinical testing: The following standards were employed in the development of this software:

FDA Recognition Number	Standard Developing Organization	Standard Designation Number And Date	Title Of Standard
13-79	IEC	IEC 62304	Medical device Software life-cycle processes
5-114	EN/IEC	EN/IEC 62366-1:2015	Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices
5-40	ISO	ISO14971	Medical devices - Applications of risk management to medical devices
12-238	NEMA	PS 3.1 - 3.20 (2011)	NEMA Digital Imaging and Communications in Medicine (DICOM) Set

FDA Recognition Number	Standard Developing Organization	Standard Designation Number And Date	Title Of Standard
5-117	ISO	ISO 15223-1:2016.	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

The software has been validated with Sedecal diagnostic x-ray generators. Compatible Sedecal generators: SFHR and SHF Series.

In recognition of possible cybersecurity threats to the software, we consulted this guidance: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff.* As a result, we updated our own internal standard operating procedures and added cybersecurity precautions to the software user manual. Software validation was conducted according to the FDA document: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.*

The User Manual contains pediatric and cybersecurity considerations. Each system is tested for proper integration prior to shipment to the end customer. Since multiple configurations are available (generator and panel models), service engineers fully test each new system upon installation at the customer site.

6. Clinical testing. Not required for a determination of substantial equivalence.

7. Substantial Equivalence Discussion.

The PRIMO S performs the same functions as the predicate using the same technological methods to produce and store diagnostic x-ray images. In all material aspects, the Sedecal and the A.T.S. APPLICAZIONE TECNOLOGIE SPECIALI S.R.L. devices are substantially equivalent to each other.

8. Substantial Equivalence Conclusion:

After analyzing bench test results, risk analysis, and standards compliance, it is the conclusion of A.T.S. APPLICAZIONE TECNOLOGIE SPECIALI S.R.L.. that the PRIMO S series of upgrade kits are as safe and effective as the predicate device, has few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.