July 11, 2025

Codonics, Incorporated
Gary Enos
Vice President, Business and Technology Integration and International Affairs
17991 Englewood Drive
Middleburg Heights, Ohio 44130

Re: K251352
Trade/Device Name: Codonics Safe Labeling System-Point of Care Station (PCS) (SLS-700i and related 610i, 620i, 630i series enabled to retrofit RFID features); Codonics Safe Labeling System-Point of Care Station (PCS) (SLS-1, SLS XXX, Multiple Models Pending Configuration)
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine For Anesthesia Or Analgesia
Regulatory Class: Class II
Product Code: BSZ
Dated: April 29, 2025
Received: April 30, 2025

Dear Gary Enos:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251352

Device Name

Codonics Safe Labeling System-Point of Care Station (PCS) (SLS-700i and related 610i, 620i, 630i series enabled to retrofit RFID features);
Codonics Safe Labeling System-Point of Care Station (PCS) (SLS-1, SLS XXX, Multiple Models Pending Configuration)

Indications for Use *(Describe)*

The Codonics Safe Label System SLS 700i and related 610i, 620i, 630i series enabled to receive RFID features and safe and effective released SLS Software provides a simple computer-based bar code scanning/RFID & printing system to automatically verify drug identity from NDC and other drug vial UDI Barcodes and (when configured and available) RFID parenteral vial information and formulary information, and to print labels embedded with RFID tags for prepared drugs and other items in use on patients during surgical procedures. Drug information is human readable on labels, 2D & Linear barcoded on labels, and RFID encoded as part of secondary container medication labels.

Codonics Safe Label System SLS 700i and related 610i, 620i, 630i series enabled to receive RFID features is generally placed in, however not limited to, the peri-operative environment to identify syringes prepared for anesthesiology use during surgery. Additional uses include producing labels for IVs and other artifacts used during a surgical procedure. SLS can also be used to print "non-surgical environment" color & text labels as required. Typical users of this system are trained professionals, including but not limited to physicians, nurses, and technicians

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.

510(k) Summary **807.92(c)**

1 Submitter Information: **807.92(a)(1)**

1.1 **Submitter:**

Codonics, Inc.
17991 Englewood Drive
Middleburg Heights, Ohio 44130
ESTABLISHMENT REGISTRATION NUMBER: 1530958
Codonics, Incorporated

1.2 **Manufacturing Facility:**

Same as above

1.3 **Representative:**

Not applicable at this time

1.4 **Contact:**

Gary W. Enos, Phone: (440) 243-1198 / Fax : (440) 243-1334
17991 Englewood Drive
Middleburg Heights, Ohio 44130

1.5 **Date:** July 10, 2025

2 Device Name **807.92(a)(2) & 807.92(a)(3)**

2.1 **Anesthesia Devices: Therapeutic Devices: Accessories**

2.2 **Classification Name:** **Gas machine for anesthesia or analgesia, Accessory**

Classification Number: 868.5160

2.3 **Classification Code:** BSZ

2.4 **Device Name:** Safe Label System (SLS-1)
Trade/Proprietary Name: Codonics Safe Labeling System-Point of Care Station (PCS)
Included Products: Codonics Safe Labeling System Family
Codonics Safe Labeling System (SLS-700i and related 610i, 620i, 630i series enabled to retrofit RFID features)
Codonics Safe Labeling (SLS XXX) RFID Series
Multiple Models Pending Configuration

2.5 **Predicate/Comparative Devices:** **807.92(a)(3)**

The Codonics Safe Label System 700i and related 610i, 620i, 630i, SLS-XXX RFID series is a continuation of the SLS device cleared to market per **K101439.** SLS 700i and related series *when equipped* with RFID is a new version release. **The Predicate used for this 510(k) is the SLS-1 SLS-500i/550i series (SLS-XXX) cleared to market per K101439 and maintained compliant per DHF safe and effective releases**

3 Device Description **807.92(a)(4)** **next page**

3 Device Description 807.92(a)(4)

3.1 Function

Drug preparation and administration in the perioperative environment are integral aspects of pharmacy, patient care clinicians, and anesthesiologist's patient care responsibilities.

Drug selection, preparation, and administration errors occur at the point of care in association with parenteral vial identification, secondary CSP container labeling, and pre-administration selection. Machine readable drug IDs & information in the form of machine-readable barcode and RFID tags serve as additional means to confirm medications (beyond human readable labeling).

Best practices for safe medication preparation and labeling in support of reducing error includes font characteristics & readability, drug class/type color coding, machine readable bar and RFID codes & formulary confirmed information being part of creation & application of secondary container CSP labeling to assist pre-administration selection and dose delivery recording.

Codonics Safe Labeling System (SLS-1) 700i and related 610i, 620i, 630i, SLS-XXX RFID series is a simple, integrated system utilizing a bar code scanner and RFID reader & encoder to confirm drug identity from NDC and other drug ID Barcoded vials and safely & automatically print labels for prepared drugs and other items in use on patients during clinical and surgical procedures. In addition to **K101439 series** machine readable barcodes, the 700i and related 610i, 620i, 630i, SLS-XXX series configurations *when equipped* with suitable near field HF, UHF, or HF/UHF RFID modules & software, allows RFID information to be read and formulary information *including 3rd party MDD ID content* to be written (*"encoded"*) to SLS label RFID tags (Passive) for use by third party applications. The labels are fully compliant with national standards and best practices focused on improving medication safety in the perioperative environment. As a MDD (Master Drug Database) intra-hospital networked device, emission & immunity safety as well as protections in the realm of cyber security is part of the safety and efficacy. The system is small enough to fit on the anesthesia supply cart and integrate seamlessly into the anesthesia workflow allowing use in the OR during patient care. Like the predicate SLS, barcode read NDC/UDI codes indexed to the approved formulary is retained as the "source of truth" for all drugs processed for labeling by SLS RFID series*.

The software components provide functions for scanning/reading vials, indexing against a "source of truth" hospital/healthcare environment managed/commissioned & verified formulary database, displaying on screen and audibly confirming drug type, printing color JCOAHO and ISO and ASTM compliant labels with 2-D barcodes ***and***, *when equippe*d with suitable HF, UHF, or HF/UHF RFID modules & software, RFID tagged information encoding on secondary container CSP labels. The system reads drug vial barcodes and produces waterproof, color labels compliant to FDA/ISMP, ASA, USP, ISO, ASTM, TJC, JCACHO.

*SLS RFID Series products maintain reliance on barcode scanned and formulary verified information to print secondary container labels *and* encode 2D and RFID tagged information to embedded SLS label RFID tags. The system label output can be integrated to function with 3rd party applications such as an AIMS system workflow to provide real-time documentation of drug administration when the syringe "2D Barcode" or RFID tag is read.

3.2 **Scientific Concepts:** In addition to the NDC or UDI (Unique Drug Identifier) barcodes found on drug vials and ampoules to identify parenteral contents, the emerging implementation of RFID technology-based healthcare services has application in medication identification, verification to reduce errors, and managing counterfeiting. SLS 700i and related 610i, 620i, 630i series enabled to receive RFID features is a series structured to read and encode HF and UHF information as the market needs emerge and develops over the next few years. Suitably configured to read barcode and (*when so configured*) embedded RFID information from drug vials for verification to a formulary of drugs approved for use by the hospital management (DOP pharmacy, anesthesiology, Dir Medical Staff, etc.), this SLS RFID series will evolve as RFID information is implemented.

While the market has not yet initiated the need for both HF and UHF implementation and specific applications, the design and testing of the SLS RFID Series included HF and UHF hardware and software to ensure safe and effective "platform ready for configured applications" when required. Future configuration releases, specific to RFID 3rd party RFID applications, will be part of the cleared to market DHF series.

The SLS formulary MDD database server, communicates with SLS Series via wire "closed intranet ethernet" or WIFI. The approved formulary, once uploaded to each SLS appliance, contains drug name, concentration, expiration, site specific warnings, dilutions, environment specific IDs, and class of drug templates (for color and pattern label standards compliance). Once a vial scanned/read at SLS identifies and confirms the parenteral vial, a secondary CSP label is displayed on the SLS touch screen along with audible indication of the drug scanned. Specific site directed medication preparation rules for approved conditions of use are localized to each "Point of Care" SLS. When vials scanned are not found in the database, a "Drug not found" indication is made and the user is warned and prompted to produce a manual label. The event finding is reported to the formulary/MDD database server for action by the authorized clinicians responsible.

3.3 **Physical And Performance Characteristics Common to 700i and associated 610i,620i,630i, SLS-XXX):**

Codonics Safe Labeling System consists of cURus, UL94, TUV certified components) :

- PC (Intel® Atom® processor) w/on-board RAM) with Ethernet interface
- SSD/Flash disk
- Microtips UMSH-9123MD Touch screen LCD end-user interface (for configuring and controlling authorized users, barcode scan and print jobs, selection of label type and manual/automatic label production, % dilution factor indications, etc.)
- Barcode scanner/decoder, ZEBRA, SE-45
- High Resolution, high speed color Label printing engine, Primera 210533
- HF RFID Control PCA (700i and equivalent when equipped to 610i,620i,630i)
- UHF RFID Control PCA ((700i and equivalent when equipped to 610i,620i,630i)
- Micro sized HF and UHF Antennae for near field, low power, read and encode functions
- Medical grade Protek External power supply, (EN60601-1) compliant power supply

Note: Codonics Safe Label System 700i and SLS XXX (models subject to release) are hardware configuration ready to execute read and write/encode RFID functions per model specified. Market requirements today are yet to demand both HF and UHF RFID in the same device; specific "to be released" configurations with fully tested and validated software will utilize the foundations submitted for clearance to market. The predicate device('s) barcode scanned and formulary verified information, used as basis to print secondary container labels and encode 2D and RFID tagged information, is well validated and accuracy verified.

HF and UHF modules configure capabilities, some which will be activated and released as future requirements for RFID arise. All (4) RFID hardware and software configurations were submitted for TUV Radio HF/UHF RFID, Electrical Safety, and Emission/Immunity Testing and compliance. The SLS-630i, configured with a fully enabled HF and UHF hardware suite, is reported as it is the "worst case" condition of the frequency range for testing and exposure. **The initial SLS RFID model with immediate application to be released is the SLS-620i (also 3rd party information specified & verified for label tag encoding aka. 700i) which is verified for HF write to and read-back from SLS label embedded RFID tags.**

Note: Codonics SLS 610i, 620i, and 630i are configurations that are **1)** prewired to accept HF or UHF RFID *and/or* **2)** partial HF or UHF RFID installations not yet enabled, *and/or* **3)** Fully HF & UHF installed and enabled to accommodate "yet to be market initiated/required" frequency management capabilities. SLS 700i, 610i, 620i are targeting release pending market & business demands; 610i~630i are hardware, radio emissions, electrical/immunity and functionally tested, however do not have a release date at the time of submission (pending clearance and specific 3rd party requirements & verification).

Summary: Next Page

Hardware and/or Functionality	SLS RFID Module for retrofit to enabled SLS Models only	SLS 610i	SLS 620i	SLS 630i	SLS 700i Keyed Feature validated and released for OEM use
	600i Prewired	**Single stack**	**Double stack**	**Triple stack**	**Double stack**
Continued next page					

Hardware and/or Functionality	SLS RFID Module for retrofit to enabled SLS Models only	SLS 610i	SLS 620i	SLS 630i	SLS 700i Keyed Feature validated and released for OEM use
	600i Prewired	**Single stack**	**Double stack**	**Triple stack**	**Double stack**
HF Antennae (front door) • **Reads HF labels on front cover for Admin Mode**	No	Installed but not enabled	Yes	Yes	Yes
UHF Antennae (front door) • **Reads UHF labels on vials and PFS**	No	Yes	Installed but not enabled	Yes	Installed but not enabled
Printer Antennae (Printer) • **Write to RFID labels**	No	No	Yes	Yes	Yes
HF Controller board	No	No	Yes	Yes	Yes
UHF Controller board	No	Yes	No	Yes	No
Read • **UHF RFID tagged vials**	No	Yes	No	Yes	No
Read • **Pharmaceutical UHF embedded labeled vials and PFS**	No	Yes	No	Yes	No
Write • **HF or UHF SLS syringe labels**	No	No	Yes, HF Only	Yes, Both HF and UHF	Yes, HF Only

RFID payload of the initial RFID version: Continued next page:

Category	ID	Data	Chars	Type	Example	bits/ char	Total bits	Notes
Admin	A	Version	2	NUM (BCD)	**01**	4	8	Each 4-bits contains one 0-9 digit. Zero padded on left.
Syringe Prep	B	BDID	10	NUM (BCD)	**000012345**	4	40	Zero padded on left. All "9"s if BDID is unassigned.
	C	Drug Name	15	STR	**PROPOFOL VERYLONGDRUGNA$**	8	120	Left Justified, space padded to right. "$" at right end indicates the drug name is truncated after 14-chars.
	D	Concentration Raw	5	RAW	**00150**	4	20	Zero padded on left.
	E	Concentration Decimal	1	POS	**2** (indicates 1.50 with data shown in "D")	4	4	
	F	Concentration Unit	2	INX	**00** (mg/mL)	4	8	Zero padded on left.
	G	Diluent	1	INX	**1** (sterilized water)	4	4	
	H	Use-by-Date	5	EPD	**00365** (Jan 1, 2011)	4	20	Zero padded on left.
	I	Use-by-Time	4	EPT	**0720** (12:00pm)	4	16	Zero padded on left.
	J	Preparers Initials	3	STR	**ABC**	8	24	Left Justified, space padded to right.

Category	ID	Data	Chars	Type	Example	bits/ char	Total bits	Notes
Source Container	K	NDC	10	NUM (BCD)	4094699331	4	40	NDC is always populated and always 10-digits.
	L	Drug Vial Expiration Date	6	NUM (BCD)	221031	4	24	Zero padded on left.
	M	Drug Vial Lot/Batch Code	20	STR	AB123456789	8	160	Left Justified, space padded to right.
Labeler	N	Source	2	NUM (BCD)	19	4	8	Zero padded on left.
	O	Drug Library Version	5	NUM (BCD)	00089	4	20	Zero padded on left.
Admin	P	Checksum	4	STR	7a2b	8	32	Checksum is always populated and exactly 4-chars.
						Total	548	

Codonics Safe Label System RFID Series HARDWARE/SOFTWARE PRODUCT Overview IS detailed as attachment to Comprehensive Device Description and Principles of Operation 2.04.01

Software to support primary functions:

- Linux OS for CPU, I/O (USB, IDE or SATA, AUDIO, Network (Ethernet/WIFI), SSD Disk access, and Touch Screen LCD display
- Specific Drivers for Touch Screen LCD, Ink Jet label printer, Barcode scanner, Ethernet/WIFI communications
- Reading of near field RFID content (when available) and writing/encoding to label RFID tag content (scanned NDC, Drug MDD ID, other payloads as validated)
- NDC or other UDI (Unique Drug Identifier, commonly known in the US as an “NDC”) drug formulary persistent repository (or database) via SSD/USB Flash, closed healthcare environment network “Ethernet/Intranet wired, closed network intranet WIFI”

In addition to these primary functions, there are other functions that are provided by the software, to include:

- System configuration (network, security, profiles, etc.)
- Security management to perform accounting and authentication of user data; add users to the User Database when requested and verify that any authenticating user credentials are correct
- Settings management global component available to all other components in the application; lookup configuration values given the appropriate configuration key
- User feedback (job and device status, errors, etc.) various events that describe the current state of the system are generated
- Job function application *managers*. Each manager is responsible for a specific set of functionalities grouped by a logical theme. For example, the Label Manager handles creating labels based on a set of Label Parameters, the Security Manager handles all issues relating to user management and authentication, and the Print Manager sends commands to and receives responses from the printer hardware

Software Application Description: The software scans user Identification (authentication) and drugs by means of a bar code, and identifies connected devices (printers, computer, and barcode scanner, near field RFID HF and UHF etc.). The software allows a label to be printed which has a color or colors identifying the type/class of parenteral vial drug for labeling of secondary container (syringe, IV bag, etc.) with the name of the drug or drugs, the units of the drug or drugs, the amount of the drug or drugs, total volume of the syringe, the user ID of the preparer, the time and date of the preparation, and a bar code (2D) identifying the contents of the syringe. The software also enables the clinician to document the pre-administration of the drug or drugs by reading the bar code printed on the SLS label at the SLS device (verification and administration mode). The 2D secondary container label barcode can be read by 3rd party applications (i.e. AIMS, PHIS, CIS, etc.) to permit transmitting the drug identification for documentation purposes.

When RFID information is printed(encoded) to the embedded SLS secondary container label tag by SLS, this information is available to be read by 3rd party RFID readers and applications. Only tags in the antenna field are read or encoded. The system also allows for the labeling of drugs which are combined with other drugs or are diluted. Finally, the software also allows the printing of blank labels as required on demand with only the clinician's ID and the date/time.

The major characteristics and functions of the family of devices include:

- Scanning the FDA required drug vial barcode directly from the vial.
  - When vial RFID information is present and the configuration of near field HF/UFH is compatible, this information can be printed to the secondary container RFID label tag for 3rd party reading. NDC BARCODE is Source of Truth
- Decoding the manufacturer issued barcode into the required FDA national drug code (NDC) or Unique Drug Identifier (UDI) number
- Referring the NDC/UDI number to a site managed formulary lookup database
- Providing audio and ISO-compliant visual "readback" of the drug name
- Providing a clinical alert if the drug vial is listed as recalled, not found, or mis-matched to MDD approved content (for DOP or Authorized Formulary Administrator to manage) in the site formulary
- Printing an easy to read, waterproof ISO 26825/ASTM D4774 compliant color label meeting The Joint Commission medication management standards and the American Society of Anesthesiologists guidelines for labeling
- Including on same label a printed barcode compliant with national standards for machine readability by 3rd party applications (for example, integration with an anesthesia information management system (AIMS) or other devices capable of barcode and the specified HF or UHF RFID tag reading
- Providing the basic information by which the printed label barcode can be read to document medication pre-administration or administration by a 3rd party application.
- Providing a 2D barcode of information to permit integration with 3rd party systems with potential for alerts if the prepared drug has expired based on preparation time and site-specific drug use criteria
- Printing labels with insertion and expiration date and time for IV lines on-demand

4 Device Intended Use: 807.92(a)(5)

4.1 The Codonics Safe Label System (SLS) and SLS Software provides a simple computer-based bar code scanning & printing system to automatically verify drug identity from NDC and other drug vial UDI Barcodes, and to print labels for prepared drugs and other items in use on patients during surgical procedures. Non-procedural medication preparation is also an intended use for SLS in the healthcare environment. The added ability of configurations to read RFID information and print/encode to a RFID tag embedded in the secondary container label provides another machine-readable form for RFID ready applications. On vial scan, an integrated formulary database reliably confirms vial barcodes with both audible and visual display of the drug name and concentration. The SLS system produces waterproof, ASA compliant color secondary container labels per ISO and ASTM standards. The software components provide the functions for scanning vials, indexing against a hospital managed formulary database, displaying on screen and audibly confirming drug type, and printing color TJC "The Joint Commission" compliant labels with 2-D barcodes and, when configured, RFID encoded information.

4.2 The use of drug class specific pattern and color per ASTM D4774 and ISO 28625 Specifications for User Applied Drug Labels in Anesthesiology is configurable by site and "Data-set". Data-sets are uniquely named configurations that may differ in drugs, colors, dilutions and comments to accommodate different practices within a single site or hospital (pediatric versus cardiac for example).

4.3 When the MDD formulary includes a 3rd party application specific information, the match is written/encoded to the RFID tag embedded in the secondary container label for 3rd party application purposes.

4.4 Additional uses include producing labels for IVs and other artifacts used during a surgical procedure.

4.5 Codonics Safe Label System (SLS) is generally placed in, however not limited to, the peri-operative environment to identify syringes prepared for anesthesiology use during surgery.

4.6 Typical users of this system are trained professionals, including but not limited to physicians, nurses, pharmacists, and technicians

4.7 Barcode scanning with SLS formulary confirmation of drug, expiration, and suitability is equivalent to the predicate device employing similar technology. Labeling or identification of the syringe with input to a 3rd party application (i.e. AIMS system) in the process of patient surgical care is equivalent in technology to previously cleared device employing similar technology. The addition of RFID is simply another machine-readable format for the well documented and validated information common to SLSs cleared per **K101439.** In addition to machine readable barcodes, the 700i and related 610i, 620i, 630i, XXX series *when equipped* with RFID module & software, allows RFID information to be read and select information content written/encoded to the SLS label RFID tags for use by third party applications. The labels are fully compliant with national standards and best practices focused on improving medication safety in the perioperative & CSP preparation environments. As a MDD (Master Drug Database) intra-hospital networked device, emission & immunity safety as well as protections in the realm of cyber security is part of the safety and efficacy.

4.8 The system/appliance maintains its original fit-form-and function and is small enough to fit anesthesia supply carts and integrate seamlessly into the anesthesia/medication preparation workflow allowing use in the OR during patient care. SLS-1 700i and related 610, 620, 630, XXX series when equipped with RFID module & software may also be used in non-OR areas for color & text labeling as needed.

4.9 **510(k) Indications for Use Statement: Prescription Use Device**

The Codonics Safe Label System SLS 700i and related 610i, 620i, 630i series enabled to receive RFID features and safe and effective released SLS Software provides a simple computer-based bar code scanning/RFID & printing system to automatically verify drug identity from NDC and other drug vial UDI Barcodes and (when configured and available) RFID parenteral vial information and formulary information, and to print labels embedded with RFID tags for prepared drugs and other items in use on patients during surgical procedures. Drug information is human readable on labels, 2D & Linear barcoded on labels, and RFID encoded as part of secondary container medication labels.

Codonics Safe Label System SLS 700i and related 610i, 620i, 630i series enabled to receive RFID features is generally placed in, however not limited to, the peri-operative environment to identify syringes prepared for anesthesiology use during surgery. Additional uses include producing labels for IVs and other artifacts used during a surgical procedure. SLS can also be used to print “non-surgical environment” color & text labels as required. Typical users of this system are trained professionals, including but not limited to physicians, nurses, and technicians

5 Device Technological Characteristics: **807.92(a)(6)**

5.1 The Codonics Safe Label System SLS 700i and related 610, 620, 630 series enabled to receive RFID features are a new series of devices that add RFID abilities to the standard K101439 cleared suite of functions in terms of products demonstrating the same completely integrated functionality. SLS RFID series are equivalent in terms of barcode read information, reference with a drug formulary list/database, and claims of similar predicate system function and intended uses.

5.2 The technology and applications are substantially equivalent to K101439 series machine readable barcodes; the 700i and related 610i, 620i, 630i, XXX series *when equipped* with RFID module & software, allows RFID information to be read and select information content written/encoded to the embedded SLS label RFID tags for use by third party applications.

5.3 The software components provide functions for scanning vials, reading/writing RFID embedded information, indexing against a hospital managed formulary database, displaying on screen and audibly confirming drug type with printing color compliant labels with 2-D barcodes. End-user feedback and confirmation improves the safety and effectiveness of the device when used as labeled.

5.4 The closed and secure healthcare environment WIFI and Ethernet functionality has an installed base of well documented sites. No event history is recorded in MAUDE or publications, and military operations as well as enterprise medical center installations have approved SLS network security and safe operation.

5.5 The system integration with 3rd party application (i.e. AIMS) can provide real-time documentation of drug administration.

5.6 The operating principle and device performance have not affected device safety or effectiveness of SLS-1

6 Testing and Equivalence: **807.92(b)(1), 807.92(b)(2) & 807.92(b)(3)**

Product Details: SLS-630i is a superset of SLS-600i, SLS-610i, SLS-700i and SLS-620i which are marketing names for reduced hardware configurations of the SLS-630i. SLS-630i is the worst-case hardware configuration of the Safe Label System and is the article equipped with 4.0.0-dev software, tested, and reported.

6.1 In the code implementation, electrical compliance tests, simulation, Bar code reading, HF RFID read and written content, UDI/NDC confirmation, TJC NPSG.03.04.01 Labeling, and clinical operations, results and outcomes have been thoroughly reviewed with proper operation and intended functions verified. Both laboratory (non-clinical environment) and surgical (clinical) tests have shown error free NDC/UDI vial reading and labeling of prepared drugs to ASA/ISO standards.

6.2 The non-clinical lab tests were conducted to verify NDC/UDI coded vials scanned with HF RFID information and printed to secondary container labels. Input codes and output read content was confirmed. Other aspects of SLS-1 color labels and content as validated as part of each release through testing is confirmed equivalent to the original Safe Label System referenced in the original K101439 submission (attachment of test ISO and ASTM labels include predicate standard and RFID labels; *Standard Medication Label ASTM and ISO Tests*).

6.3 The clinical application of every release of SLS-1 Safe Label system is documented per DHF and equivalent to the original K101439 submission

6.4 The production ready SLS-1 device is documented per DHF files for all releases and has been designed under ISO 13485 certified controls and has passed the series of electrical safety and emission/immunity for healthcare environment tests. SLS-1 600I, 610I, 620i, and 700i (and pending SLS-XXX) are TUV certified compliant to listed standards herein including Additional Information Reasonably Deemed Necessary to access safe and effective use

6.5 The system reliably reads vial drug ID information from barcodes and, *when available*, RFID tags, and produces fully compliant, waterproof, color secondary container labels. The read-to-label time (open syringe, needle and vial, draw drug into syringe and apply completed label) provides efficiency in typical workflows when compared to using standard labeling with handwritten time, date, concentration and initials. SLS 700i and related 610i, 620i, 630i, SLS-XXX series *when equipped* with RFID system prototypes:

1. Passed electrical safety and emission tests with issued certification (environment compatibility and interoperability).

2. Radio frequency and exposure criteria for EMC compatibility, CISPR 11 limits of radio disturbance, safe use and FCC RF Part 2. 1091and RSS-102 Issue 5 Exposure
3. Laboratory tests of input information processing to RFID printed/tagged output has verified error free accuracy and precision. The 700i and related 610i, 620i, 630i, SLS-XXX series has technically updated a touch screen display and high-resolution printer configuration. The end-user acceptance of screen readability, color, responsiveness and printed label resolution (including barcode clarity) has been documented in pre-release testing.
4. Micro antennae limited the field of reading and writing in combination with lower power to act in near field. Discrimination of presented versus non-presented tags is managed and writing to already written tags prevented via unique identification.

807.92(d)

Emissions EMC Test plan attached and part of TUV reports Section 3
IEC 60601-1-2:2014+A1:2020, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests
CISPR 11:2015+A1:2016+A2:2019 - Limits and methods of measurement of radio disturbance, Characteristics of industrial, scientific and medical radio frequency equipment

FCC Class A and IEC 60601-1-2: Ed. 4 for Professional Healthcare Facilities

Reports attached:

a) 2022_12_15 Codonics SLS-630i EMC Report TR 3581 V3.pdf
b) 2023_01_27 US22SOCD.003_Codonics_SLS-630i__EMC Test Report 60601-1-2_extsigned.pdf (**Full Test of SLS-630i)**
c) 2023_02_03 US22DGC8.002 Safe Label System Coexistence Report (Signed).pdf (**Medical Coexistence test of SLS-630i to AIM Standard 7351731: 2021** - **Tested HF and UHF RFID immunity**)
d) 2024_01_09 US23PHKB 001 Rev 03_extsigned.pdf (**test of SLS 630i with new LCD Display**)
e) Immunity Test Compliance Statement TS IEC60601-4-2

Safety
Electrical Safety:
North America safety report (ANSI/AAMI ES60601-1, CAN/CSA-C22.2 No. 60601-1:14, etc.):

a) Reports attached: 2023_11_30 31890653.007 cTUVus 01162024_signed_extsigned.pdf
b) Rest of world safety report (IEC 60601-1:2012 Ed 3.1):
c) 2023_11_30 31890653.008 CE i60601_1k 12012023_signed_extsigned.pdf

cTUVus Certificate (Safety Compliance):

d) 2023_06_09 CU72181179.02 31890653.005.pdf

The subject device has no patient contact however has been designed to meet patient contact and anesthesia environment electrical safety (IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012, IEC 60601-1-2:2014+A1:2020 and 61000: Medical electrical equipment safety standards (electrical safety, emissions).

Specific Radio Electromagnetic Compatibility (EMC) Test Reports UHF and HF near field antennae/controller configurations with Statement of Compliance to FCC Part 2.1091, and to CFR 47 Part 15.247: 2022 and RSS 247: 2017 (and others as noted), using SLS SW 4.0.0-dev

- US22ADFH.002, SLS-1 with Front Cover UHF Antenna: Abracon APAG-0007
- US22DS8P.002, SLS-1 with Print Path UHF Antenna: Mikroe-4503
- US22TQST.002, SLS-1 with Front Cover HF PCB Loop Antenna
    - CFR 47 Part 15.225:2022 and RSS-210: Issue 10
    - Emissions: ANSI C63.10-2013, KDB 558074 D01 DTS Measurement Guidance v05r02, KDB 662911 D01 Multiple Transmitter Output v02r01, FCC KDB 996369 D04 Module Integration Guide v02.

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- US220QSE.002, SLS-1, Print Path UHF Antenna Mikroe-4503
  - RSS-102 Issue 5, IEEE C95.3-2002
- US224M8H.002, SLS-1 with Print Path HF PCB Loop Antenna
  - Emissions: ANSI C63.10-2013, KDB 558074 D01 DTS Measurement Guidance v05r02, KDB 662911 D01 Multiple Transmitter Output v02r01, FCC KDB 996369 D04 Module Integration Guide v02.

The device family does not control, monitor or otherwise affect any devices directly connected to or affecting the patient. Medical personnel review the results and inputs processed by the Codonics SLS and offers ample opportunity for competent human intervention in the case of a malfunction or other failure.

Quality System
QSR compliance to 21 CFR Part 820

Laboratory and preliminary tests have documented effective application, throughput, reliability, and expected results consistent with the SLS-1 K101439 predicate devices maintained per DHF and currently in commercial distribution and additional verification and validation testing is planned prior to release.

Attachment “Predicate Comparison SLS_BSZ25 Substantial Equivalence” 2.04.05 of this submission includes the original K101439 information and provides a comparison of the Codonics Safe Label System (SLS-1) predicate technology to the Safe Label System 700i and related 610i, 620i, 630i, XXX series device(s) and describes how any differences of note are substantially equivalent.

APPLICABLE PERFORMANCE STANDARDS: Codonics has designed the Safe Labeling System to comply with the following standards:

6.6 Recognized Consensus Standards (submitted, reviewed) with original 510(k) **K101439** with respect to prepared drug labeling & devices

- **ASTM D4774 (versions 06, 11, 11-R17)** Standard Specification for User Applied Drug Labels in Anesthesiology: size, color and pattern, and type used on labels applied to unlabeled syringes filled by the users or their agents to identify the drug content. Not intended to cover labels applied by the drug manufacturer.
- **ISO 26825:2008, 2020** Anesthetic and respiratory equipment – User-applied labels for syringes containing drugs used during anesthesia – Color, design and performance
- **ASTM D4267 2021**, Standard Specification for Labels for Small-Volume (100 ml or less) Parenteral Drug Containers: contrast; label; label content; legibility; legibility test; parenteral drug; type size applied to unlabeled volumes filled by the users or their agents to identify the drug content
- **ASTM D6398 8r14**, Standard Practice to Enhance Identification of Drug Names on Labels: covers the shape, size, color, layout, typeface, and bar-coding practices, use of TALLMAN lettering
- **National Drug Code (NDC) number (21 CFR 201.25)**, Bar Code Label Recognition
- **Joint Commission on Accreditation of Healthcare Organizations NPSG. 03.03.01, 03.04.01, and 03.05.01** Re: Enhanced ID of Look Alike/Sound Alike Drugs, Labeling all medications, syringes, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings, ID for increased safety of anticoagulant preparations
- **ISMP 2024**-The Institute for Safe Medication Practices and the **FDA**-U.S. Food and Drug Administration **Look-Alike Drug Name Sets With Recommended Tall Man Letters**
- **ASA GUIDE ON LABELING OF PHARMACEUTICALS FOR USE IN ANESTHESIOLOGY**

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- **IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012, IEC 60601-1-2:2014+A1:2020 and 61000:** Medical electrical equipment safety standards (electrical safety, emissions)

7 Hazard Analysis and Safety Concerns

7.1 Ultimate use of SLS series is under the control of clinicians, pharmacists, and nursing practitioners. Human intervention and acknowledgement are required at every step and SLS provides a verification mode to read bar codes, tag information, and expiration status. No automated decision processes tied to patient care are involved with SLS operation.

7.2 Codonics considered the risks to be mitigated that could result in potential human injury if wrong drug as labeled is administered:

a- misreading of barcode

b- failure to database index proper drug

c- failure to visibly or audibly validate the drug

d- failure to print the correct color label and/or drug identification or RFID tag information on label

e- failure to present the correct prepared medication barcode on secondary label

f - reading or writing/encoding the wrong RFID tag or multiple tags

7.3 Hazard analysis on this product has been performed throughout the product concept and testing phases of the product development and implementation. This process has emphasized:

- Identification of potential hazards, their causes and their effects
- Development of methodologies to control the occurrence of hazards and to constrain their effects
- Determine any effect on patient safety and system effectiveness
- The FMEA Electrical, Software and Supplemental System Actions to mitigate potential risks have been completed with action taken described as part of the FMEA/risk reports
- Risk analysis has documented minimal to non-existent safety concerns with benefits out weighing and residuals noted.

The potential hazards associated with this product are not different than those of other devices in this category and the cleared to market predicate device. These are primarily related to the failure of computer system components, and may be variously obviated by decisions taken by the end users of the product. Any failure of SLS, while being inconvenient, would not halt patient care or safe medication practices. Clinicians ultimately revert to manual procedures of medication preparation labeling and administrative documentation. None of the failures are expected to materially contribute to patient death or injury.

8 Nonclinical and Clinical Tests Conclusion:

8.1 SLS RFID series (600i equipped and configured as 610i, 620i, 630i and 700i) is as effective and safe as the predicate K101439. The RFID functionality is stable and functions precisely as intended. Each RFID utility is verified prior to release with the intended 3rd party application that will use the embedded RFID label content. As RFID requirements in the HF and UHF frequency(s) space emerge, SLS RFID Series will process MDD and Vial based RFID information for specified writing to the label tag. Tag contents are verified with the 3rd party reader and configurations are released accordingly; part of the DHF for the series by type.

8.2 Codonics has concluded the control and verifications documented at each site and for each specific configuration of RFID condition, and the safe and effective use of the range of hardware & software to compliment the intended uses, confirms SLS RFID series suitable for clearance to market.

8.3 Codonics chose to modify a DHF compliant cleared to market SLS-1 model designated SLS 600i for design verification of four (4) HF, UHF, or HF/UHF RFID modules & software configurations as noted herein. While the 600i is cable & I/O pre-wired for RFID hardware, it is not RFID enabled. HF and UHF modules configure antenna and controller capabilities, some which will be activated and

released as future requirements for RFID arise. All (4) RFID hardware and software configurations were submitted for TUV Radio HF/UHF RFID Electrical Safety, and Emission/Immunity Testing compliance. The SLS-630i, configured with a fully enabled HF and UHF hardware suite, is reported as it is the “worst case” condition of the frequency range for testing and exposure. The initial SLS RFID model with immediate application for HF to be released is the SLS-620i (also 3rd party information specified & verified for label tag encoding aka. 700i).

8.4 The use of a “predicate SLS-600i” is referenced as a “base project “SLS-1 configuration for the purpose of RFID development test units with various configurations of RFID hardware. With wiring to support various configurations of RFID hardware, this base model serves to maximize utility for emerging HF and UHF targeted release models. The roadmap configurations include SLS 610i, 620i, and 630i as a series with the SLS-XXX provision to cover pending models subject to test and release with specific feature keys to meet 3rd party applications (700i/800i would follow in this notation). For the purpose of RFID configuration engineering and testing, a completely tested SLS-1 model SLS-600i was HF/UHF hardware & 4.0.0-dev software configured to verify proof of concept, configuration stages/phases, and laboratory performance testing by TUV, F2, and Laird independent laboratories to confirm safe and effective emissions, immunity, and exposure compliance.

8.5 Third Party Test Data to verify and validate drug labeling color, contrast, and content and RFID data coding and read-back confirmed safe and effective operation consistent with intended use.

8.6 Medication Label ISO 26825 and ASTM D-4774 consistency tests confirm drug class color & template type, label contents, and characteristics specified in standards submitted.

8.7 Preliminary Verification Test SLS Configurations Safe Label System Confirmation of Functionality reporting greater than 10,000 RFID labels of 25 drugs in the various drug class colors and RFID payload yielded Pass conditions and meeting intended use and safe and effective use.

It is our conclusion that there is no hardware or software component, operating in a properly configured environment, whose latent design defect would be expected to result in death or injury of the patient. Thus the “**level of Concern” is reduced to “Moderate” in the 4.0.0.dev version and target 4.0.0. release device**.