



Food and Drug Administration
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October 30, 2015

Philips Medical Systems
Kristen Phillips, RHIA, CTFL
Regulatory Affairs Specialist
3000 Minuteman Road, MS 4304
Andover, Massachusetts 01810-1099

Re: K151366

Trade/Device Name: CS770 IntelliSpace Critical Care and Anesthesia, Release H.0
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical cathode-ray tube display
Regulatory Class: II
Product Code: DXJ, NSX
Dated: September 29, 2015
Received: October 2, 2015

Dear Ms. Phillips:

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" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tina
Kiang -S

for Erin I. Keith, M.S.

Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151366

Device Name

CS770 IntelliSpace Critical Care and Anesthesia, Release H.0

Indications for Use (Describe)

Intended for use in the data collection, storage, and management with independent bedside devices, and ancillary systems that are connected either directly or through networks. The device is indicated for use whenever there is a need for generation of a patient record and computation of drug dosage in all areas patient care is given in the hospital, including critical care and anesthesia areas.

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

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

Reference 510(k) Number:

K151366 CS770 IntelliSpace Critical Care and Anesthesia, Release H.0

1. The submitter of this premarket notification is:

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This summary was prepared on 29 October 2015.

2. The name and classification of the device:

Trade Name: CS770 IntelliSpace Critical Care and Anesthesia, Release H.0.

Common name: Clinical Information Management System

Classification:

| Classification | ProCode | Description |
|----------------------|---------|--|
| 870.2450, II | DXJ | Display, Cathode-Ray Tube, Medical |
| Secondary Prod Code: | | |
| | NSX | Software, transmission and storage, patient data |

3. Device Description:

The CS770 IntelliSpace Critical Care and Anesthesia software (Release H.0), a modified version of the IntelliVue Clinical Information Portfolio which was last cleared under premarket notification number

K100272. ICCA is a software only product used for charting and data management, offers clinical decision and clinical workflow support for critical care environments, intra-operative anesthesia, and the anesthesia-critical care continuum. Integrating information from patient vital sign monitors and ancillary bedside devices, hospital systems such as CPOE and laboratory, and clinical documentation, ICCA uses advisories and evidence-based medicine bundles to provide information to clinicians. In addition ICCA provides a powerful Data Analysis and Reporting (DAR) database and reporting toolset for the critical care and anesthesia environments.

4. The CS770 IntelliSpace Critical Care and Anesthesia, Release H.0 software is substantially equivalent to the previously cleared IntelliVue Clinical Information Portfolio, Release E.0 marketed pursuant to K100272.

5. Indications for Use

The device has an updated Indications for Use and Intended Use Statement:

Intended for use in the data collection, storage, and management with independent bedside devices, and ancillary systems that are connected either directly or through networks. The device is indicated for use whenever there is a need for generation of a patient record and computation of drug dosage in all areas patient care is given in the hospital, including critical care and anesthesia areas.

6. The major modifications are as follows:

The purpose of this submission is to formally document the renaming of the product to the Philips CS770 IntelliSpace Critical Care and Anesthesia (ICCA) as well as to update the 510(k) filing to include the following software changes:

Medical Reference capability

Third party medical reference information will be displayed to the end user at the time of entering an order. Depending on the configuration, the end user may be given the opportunity to review the medical reference information provided and cancel or modify the order.

Patient Data Security

Patient data security is being enhanced in relation to controlling and tracking of users actions when they access restricted patient records.

Formulary Upload

A new tool launched from ICCA's system management tools which allows the following functions:

- Exporting ICCA configuration into XML files
- Importing XML files into an existing ICCA system

User Interface (UI) Streamlining

The UI enhancements introduce a new "look" to the patient chart container (the parent window that hosts patient data), Patient Census, Notes and Forms. Preexisting chart functionality is retained with some minor exceptions; the user's navigation has been modified and the previous menu approach is replaced with an industry-standard ribbon approach. The new UI involves implementing

a ribbon that replaces most of the menu and toolbar commands (available from the chart, census, and personal organizer), a user login / logout area, a notification area (for reminder, advisory, notification icons), and a patient area (for the patient picker and infostrip) which is only visible from the patient chart. The core chart functionality (flowsheet) remains the same as in prior releases.

Discharge Management Report

Enhance the discharge document to accommodate more data points, customization and capture data available in the record at the time the report is generated.

Medication Order co-signing

In many clinical environments, there is a list of drugs that the customer considers to be restricted and need two clinical approvals for ordering of the drug. ICCA supports:

- Configurable list of drugs that need the co-signing
- Holding the order release until one additional clinician has approved the original order. No interventions are generated until additional clinician approves the order.
- Allow the customer to designate specific users who have co-signing authority
- Modify the existing order workflow to present a co-signing authentication/opportunity for the end user.
- Log and traceability on all activities related to co-signing in orders audit trail
- Configuration is done as a check box on the drug in the pharmacy product editor
- Generate a reminder icon, an update to the reminder document
- If the user has cosign permission, it is configurable if the order can continue or be held.
- Co-sign exists whenever the order is created or modified.
- Co-sign impacts all types of orders that uses that drug.
- Inbound interfaces are not impacted

7. Comparison with predicate:

| Comparative Characteristic | Predicate Device IntelliVue Clinical Information Portfolio, Release E.0 | Subject Device CS770 IntelliSpace Critical Care and Anesthesia, Release H.0 |
|-----------------------------------|--|--|
| Device Name | IntelliVue Clinical Information Portfolio, Release E.0 | CS770 IntelliSpace Critical Care and Anesthesia, Release H.0 The below indications for use have been updated to include the implied use in the name for critical care and anesthesia areas. |
| Intended Use | Intended for use in the data collection, storage, and management with independent bedside devices, and ancillary systems that are connected either directly or through networks. | Intended for use in the data collection, storage, and management with independent bedside devices, and ancillary systems that are connected either directly or through networks. |
| Indications for use | The device is indicated for use whenever there is a need for generation of a patient record and computation of drug dosage. | The device is indicated for use whenever there is a need for generation of a patient record and computation of drug dosage in all areas patient care is given in the |

| Comparative Characteristic | Predicate Device IntelliVue Clinical Information Portfolio, Release E.0 | Subject Device CS770 IntelliSpace Critical Care and Anesthesia, Release H.0 |
|---|---|--|
| | | hospital, including critical care and anesthesia areas. |
| Population | No direct patient connection. As this software is only intended for use in data collection, storage, and management; the performance of the software does not change with different patient populations. | Same |
| Environment | Hospital | Same |
| Operating Principle | Data Management (charting and reporting) | Same; with the addition of the Patient Analytics Platform option. |
| Electronic Patient Record | Configurable Patient Record usually consisting of Flowsheets, Notes and Forms, Medication Administration Record, Patient Summary, History and Physical, Worklist, procedure and diagnosis coding | Same; with UI enhancements, Discharge Management report and Medication co-sign. |
| Census | Patient Census screen showing patient status | Same |
| Configuration Editors | A set of configuration editors are provided that allow trained personnel to configure the Patient Record documents and reports. Programming language skill not required. | Same, plus ability to import/export configuration (known as Formulary Upload) |
| Reporting Capability | Generate paper copy reports for the patient record, including audit trail. | Same |
| Drug Calculator | Present | Same |
| Calculations Engine & Clinical Advisories | Present | Same Calculations Engine with same clinical advisories; added Deep Vein Thrombosis advisory. |
| Alarm functionality | None | Same |
| Measurement functionality | None | None |
| Technology | ICIP follows deployment model similar to Microsoft technologies such as clustering. ICIP was designed to be a cost effective solution which handles single unit, standalone starter configurations to large scale, multi-unit installations. Reference the ICIP Architecture Overview in Appendix A, ICIP System Architecture Enterprise View diagram in Appendix B and the 865209 IntelliVue Clinical Information Portfolio Release E.00 Technical Data Sheet in Appendix C. | Same |
| Operating Systems | Windows XP Professional, | Windows 7; |

| Comparative Characteristic | Predicate Device IntelliVue Clinical Information Portfolio, Release E.0 | Subject Device CS770 IntelliSpace Critical Care and Anesthesia, Release H.0 |
|---|--|---|
| | Windows Server 2008, Enterprise Edition; SQL Server 2008 | Windows Server 2008 R2, Enterprise Edition; Windows Server 2012 R2, Enterprise Edition; SQL Server 2008 R2/2012, Enterprise Edition |
| Programming language | Microsoft .NET C# | Same |
| Remote Service Network capability | To gain remote access, the user can run Remote Desktop client, or Terminal Server sessions on any appropriately configured Windows Terminal Server Host. | Same |
| Interfaces/Data Acquisition – Philips Monitoring System | HL7 interface from Philips Information Center server | Same |
| Interfaces/Data Acquisition | Device Link II (K041942) and DataCapsule Information using Ethernet LAN standard protocol to interface with other hospital networks. | Same, plus IntelliBridge System |
| Interfaces/Hospital Information System – Inputs | ICIP interfaces to other hospital systems through Health Level 7 (HL7). | Same |
| Interfaces/Hospital Information Systems - Output | Patient Data export; Document Export | Same |
| Auto-Charting | Automatically stored device data without user intervention | Same |
| Data Analysis and Reporting | DAR provides users a location to query and develop patient data reports without impacting the performance of the ICCA charting systems. | Same |
| Medical Reference | N/A | Third party medical reference information displayed to user. |
| User Access & Patient Data Security | User Authentication services and user roles to include logging for audit trail information. | Individual Patient lock, Break glass (user emergency access with logging) and enhanced logging service. |

8. The technological characteristic changes of this device are the design changes as follows:
- The electronic patient record is the same with additional UI enhancements, Discharge Management report and medication co-sign.
 - The configuration editors are the same plus the ability to import/export formulary configuration
 - The Calculations Engine & Clinical Advisories are the same with the addition of the Deep Vein Thrombosis advisory.

- The operating system did not include a design change, however the device is verified for compatibility with the updated versions of Windows (as listed in the table above)
- The Interfaces/Data acquisition in the devices are the same with the addition of interfacing with IntelliBridge System.
- The device has added a third party medical reference display.
- The user access & patient data security is the same with the addition of enhanced logging, individual patient lock and user emergency access with logging.

9. Standards and Guidance used:

| Standard Number & Date | Standard Title | Recognition Number |
|-----------------------------------|---|--------------------|
| ISO 15223-1: 2012 | Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied | 5-90 |
| IEC 62304: 2006 | Medical device software. Software lifecycle processes | 13-32 |
| AAMI/ANSI/IEC 62366: 2007/(R)2013 | Medical devices. Application of usability engineering to medical devices | 5-67 |

The following FDA documents were used for guidance:

- “The New 510(k) Paradigm, Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications”, issued March 20, 1998.
- “Guidance for Industry and FDA Staff, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”, issued May 11, 2005.
- “Guidance for FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices”, issued September 9, 1999.
- “Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software” issued January 14, 2005.
- “Guidance for Industry and Food and Drug Administration Staff; The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]”, Document issued on: July 28, 2014
- “Use of Standards in Substantial Equivalence Determinations”, March 12, 2000.
- “Guidance for Industry”, Alternative to Certain Prescription Device Labeling Requirements, issued January 21, 2000.
- “Guidance for Industry and FDA Staff, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”, issued May 11, 2005. “General Principles of Software Validation; Final Guidance for Industry and FDA Staff”, January 11, 2002

- “Guidance for Industry and Food and Drug Administration Staff”; Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Document Issued on: October 2, 2014
- “Guidance for Industry and Food and Drug Administration Staff, Mobile Medical Applications”; Document issued on: September 25, 2013

10. Non-clinical Testing:

Verification, validation, and testing activities, where required to establish the performance, functionality, and reliability characteristics of the new device with respect to the predicate are performed. Testing involved system level tests, performance tests, and performance testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence.

11. Conclusions from Non-clinical testing:

The CS770 IntelliSpace Critical Care and Anesthesia, Release H.0 software meets all reliability requirements and performance claims; this supports a determination of substantial equivalence.