June 18, 2021

Stryker Corporation
Cathy Friday
Sr. Staff Regulatory Affairs Specialist
3800 E. Centre Avenue
Portage, Michigan 49002

Re: K202964
    Trade/Device Name: iBed Wireless with iBed Mobile
    Regulation Number: 21 CFR 880.5100
    Regulation Name: AC-Powered Adjustable Hospital Bed
    Regulatory Class: Class II
    Product Code: FNL
    Dated: May 13, 2021
    Received: May 17, 2021

Dear Cathy Friday:

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,

CAPT Alan M. Stevens
Acting Director
DHT3C: Division of Drug Delivery and
    General Hospital Devices,
    and Human Factors
OHT3: Office of GastroRenal, ObGyn,
    General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number *(if known)*
K202964

Device Name
iBed™ Wireless with iBed™ Mobile

Indications for Use *(Describe)*
The intended use of the iBed™ Wireless with iBed™ Mobile accessory is to assist healthcare professionals in setting, adjusting, and monitoring specific bed parameters from a different location within the healthcare delivery organization's campus. The iBed™ Wireless with iBed™ Mobile accessory is intended to be used only with Stryker Medical's AC-powered adjustable hospital beds that have been verified and validated with the iBed™ Wireless software and is not intended to provide information on non-Stryker Medical beds. The iBed™ Wireless with iBed™ Mobile accessory is intended to only transfer bed status and parameter data and does not store this data.

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.

<p style="text-align:center">Traditional 510(k) Summary
K202964</p>

I. SUBMITTER

Stryker Medical
3800 E. Centre Ave
Portage, MI 49002

Cathy Friday
Sr. Staff Regulatory Affairs Specialist
e: catherine.friday@stryker.com
t: (269) 312-0684

Date of Summary: 13 May 2021

II. SUBJECT DEVICE

Device Trade or Proprietary Name:	iBed™ Wireless with iBed™ Mobile Model 5212
Common or Usual Name:	AC-Powered Adjustable Hospital Bed (Accessory)
Regulation Number:	21 CFR 880.5100, 510(k) Exempt
Classification Name:	AC-Powered Adjustable Hospital Bed
Product Code:	FNL
Class:	Class II
Review Panel:	General Hospital

III. PREDICATE DEVICE

iBed™ Wireless with iBed™ Awareness, K103536
(Stryker Corporation)

IV. DEVICE DESCRIPTION

The Model 5212 iBed™ Wireless with iBed™ Mobile consists of iBed™ Wireless (WiFi module) and the iBed™ Mobile software application that is intended to be used with Stryker Medical's AC-powered adjustable hospital beds within a healthcare delivery organization. The iBed™ Wireless with iBed™ Mobile device accessory is an updated software platform that provides bi-directional data transmission between Stryker Medical's AC-powered adjustable hospital beds equipped with iBed™ Wireless, the healthcare delivery organization's server (owned and maintained by the healthcare delivery organization), and a healthcare professional's handheld electronic device. It is a convenience tool facilitating bi-directional data transmission of bed status data and parameters allowing healthcare professionals the ability to set, adjust, and monitor bed status from a remote

location within the healthcare delivery organization facility. Table 1 provides an overview of the specific bed parameters utilized by the iBed™ Wireless with iBed™ Mobile device accessory.

As a security measure, the iBed™ Wireless with iBed™ Mobile device accessory is only available to healthcare professionals connected to their healthcare delivery organization's information system network and is not accessible or operational by the public. The iBed™ Wireless with iBed™ Mobile device is intended to only transfer bed status and parameter data and does not store this data. All bed functions and parameters remain available at bedside.

The iBed™ Wireless with iBed™ Mobile device accessory is not intended to provide automated treatment decisions or be used as a substitute for professional healthcare judgement.
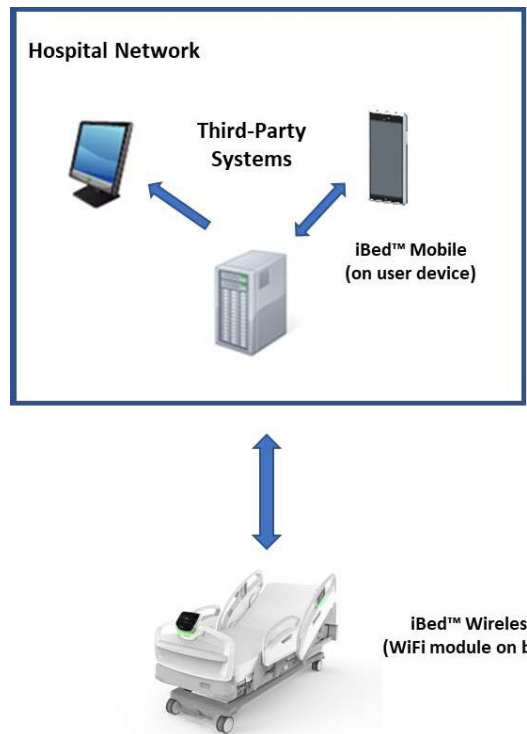

Figure 1: iBed™ Wireless with iBed™ Mobile System

iBed™ Wireless with iBed™ Mobile Device Accessory Components

iBed™ Watch

When enabled, iBed™ Watch provides visual cues when changes are made to the selected bed settings: low height, siderails up, head (back rest) angle, bed exit zone, and bed flat. Note: The iBed™ Watch function was previously marketed as iBed™ Awareness and cleared under the predicate device 510(k) submission (K103536).

iBed™ Wireless (WiFi Module)

The iBed™ Wireless software and hardware system used in Stryker Medical beds enabled with iBed™ Watch allows remote viewing of bed status. The WiFi radio containing the iBed™ Wireless software allows bi-directional data transmissions from the healthcare delivery organization's central Information Systems server and the Stryker Medical bed. A healthcare professional can set, adjust, and monitor bed status parameters from a non-bedside location within the healthcare delivery organizations facility.

iBed™ Mobile

The iBed™ Mobile application is a convenience tool that allows a healthcare professional the ability to set, adjust, and/or monitor bed status parameters from a non-bedside location anywhere within the healthcare delivery organizations facility. The iBed™ Mobile device accessory can only function with Stryker Medical beds enabled with iBed™ Wireless software. The iBed™ Mobile application run on Apple iOS Revision 14 or greater operating system. Note: All bed functions remain usable at bedside when using the iBed™ Mobile device accessory.

Viewing and/or enabling of specific bed parameters can be conducted from a mobile device using iBed™ Mobile. Stryker Medical will upload iBed™ Mobile software upgrades to relevant mobile application stores to be downloaded by the user. Upgrades will be sent to the Stryker Medical bed via the iBed™ Platform and iBed™ Wireless where the healthcare professional will have to accept the upgrade at bedside to download the update. Table 1 contains a list of the Stryker Medical Bed parameters that can be managed using iBed™ Wireless with iBed™ Mobile.
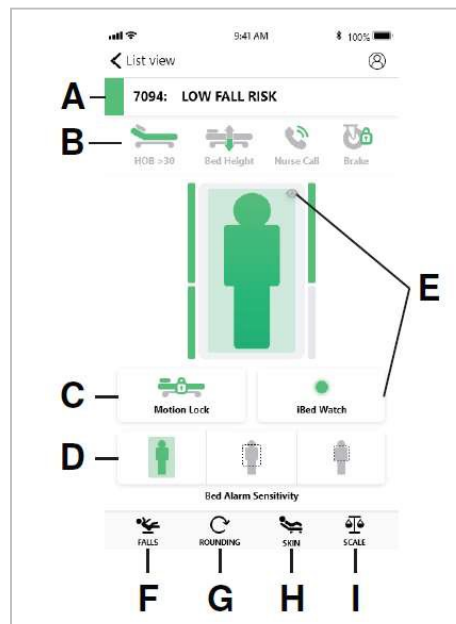

Figure 2: iBed™ Mobile Room View Screen Explanation

Table 1: Bed Status Parameters Using iBed™ Mobile

	iBed™ Mobile Function	Status	Parameter Description
A	Location/Patient Status	View Only	Displays room location, patient fall risk, and bed protocol notifications, bed serial number
B	Bed Status	View only	Displays HOB >30, bed height, nurse call connected, brake, siderail position, bed exit sensitivity.
C	Motion Lock	Enable only	Locks bed motion.
D	Bed Exit	Enable only	Activate and select bed exit sensitivity.
E	iBed Watch	Enable only	Activates iBed™ Watch.
F	Falls	View only	Displays falls tab (Falls tab)
G	Rounding	View only	Displays rounding tab (Rounding tab)
H	Skin	View only	Displays skin tab (Skin tab)
I	Scale	View only	Displays scale tab (Scale tab)

V. INTENDED USE STATEMENT

The intended use of the iBed™ Wireless with iBed™ Mobile accessory is to assist healthcare professionals in setting, adjusting, and monitoring specific bed parameters from a different location within the healthcare delivery organization's campus. The iBed™ Wireless with iBed™ Mobile accessory is intended to be used only with Stryker Medical's AC-powered adjustable hospital beds that have been verified and validated with the iBed™ Wireless software and is not intended to provide information on non-Stryker Medical beds. The iBed™ Wireless with iBed™ Mobile accessory is intended to only transfer bed status and parameter data and does not store this data.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Design verification and validation testing was performed on the iBed™ Wireless with iBed™ Mobile and included software verification, bench performance, and design validation. Software verification testing was conducted to ensure the bi-directional capability performed according to specification. Bench performance testing was conducted to ensure the bed software, firmware, and iBed™ Mobile performed together according to specification. Design validation testing was conducted in a simulated-use environment by health care professionals. Users were successfully able to set, adjust, and monitor bed status parameters from remote locations within the healthcare delivery organization as intended.

Note: In the following table, the "Subject Device" is defined as the iBed™ Wireless with iBed™ Mobile device and the "Predicate Device" is defined as the iBed™ Wireless with iBed™ Awareness (K103536).

Table 2: Comparison of Technological Characteristics with the Predicate Device

Device Characteristic	Subject Device iBed™ Wireless with iBed™ Mobile (K202964)	Predicate Device iBed™ Wireless with iBed™ Awareness (K103536)	Differences
Device Trade or Proprietary Name	iBed™ Wireless with iBed™ Mobile	iBed™ Wireless with iBed™ Awareness	Addition of iBed™ Mobile iBed™ Awareness was renamed iBed™ Watch.
Product Model Number	5212	Same	None
Common or Usual Name	AC-Powered Adjustable Hospital Bed (Accessory)	Same	None
Regulation Number	21 CFR 880.5100 510(k) Exempt	Same	None
Classification Name	AC-Powered Adjustable Hospital Bed	Same	None
Product Code	FNL	Same	None
Class	Class II	Same	None
Review Panel	General Hospital	Same	None
Intended Use	The iBed™ Wireless with iBed™ Mobile device accessory's intended use is to provide healthcare professionals the ability to set, adjust, and monitor specific bed parameters from a remote location within a healthcare delivery	The intended use for the iBed™ Wireless with iBed™ Awareness is to assist clinical staff to monitor bed parameters on specific Stryker Medical beds. The monitored parameters include bed brakes, side rail position, bed exit, etc.	Subject device can set, adjust, and monitor specific bed status parameters. Predicate device can only monitor bed status. The Intended Use statement for the iBed™ Wireless with iBed™ Mobile device is not identical to the predicate

Device Characteristic	Subject Device iBed™ Wireless with iBed™ Mobile (K202964)	Predicate Device iBed™ Wireless with iBed™ Awareness (K103536)	Differences
	organization's facility using bi-directional data communication. The desired bed parameters will be initially set by healthcare professionals at bedside. The iBed™ Wireless with iBed™ Mobile device accessory is intended to be used only with specifically enabled Stryker beds that have been verified and validated with the iBed® Wireless software and is not intended to provide bed status information for non-Stryker beds. Patient health information is not communicated or stored.	The desired bed parameters will be set by clinicians at the bedside. The iBed™ Wireless software is intended to be used only with specifically enabled Stryker Medical beds that have been verified and validated with the iBed™ Wireless software and is not intended to provide bed status information for non-Stryker Medical beds. The iBed™ Wireless software is not intended to communicate any patient status information nor to permanently store any type of data.	device; however, the differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for the ability to monitor the patient's bed parameters, either from a stationary nurse station as in the predicate device or via the mobile application in the subject device.
Indications for Use	The intended patient population is dependent on the Stryker Medical bed location within the healthcare delivery organization. The iBed™ Wireless with iBed™ Mobile accessory does not change the existing populations for which these beds serve.	Same	None

Device Characteristic	Subject Device iBed™ Wireless with iBed™ Mobile (K202964)	Predicate Device iBed™ Wireless with iBed™ Awareness (K103536)	Differences
Primary Function	Bi-directional data communication for activating or viewing bed status parameters.	One-way data communication for viewing bed status parameters.	Subject device utilizes bi-directional data transmission that allow remote activation and viewing.
Intended Patient Population	Patients confined to a healthcare delivery organization bed (not for use in a home or non-institutional long-term care facility setting).	Same	None
Intended Users	Healthcare Professionals	Same	None
Operational Environment	Must be used in a healthcare delivery organization.	Same	None
Bed Status Parameters - Location/Status	- Remote viewing of: - Room location - Patient fall risk - Bed protocol notifications - Bed serial number	- Remote viewing of: - Room location	Subject device added remote viewing of patient fall risk, bed protocol notifications, and bed serial number.

Device Characteristic	Subject Device iBed™ Wireless with iBed™ Mobile (K202964)	Predicate Device iBed™ Wireless with iBed™ Awareness (K103536)	Differences
Bed Status Parameters - Bed Status	• Monitoring of: o HOB angle >30 o Bed height o Nurse call connected o Brake (locked/unlocked) o Siderail position o Bed exit zone and sensitivity	Same	None
Bed Status Parameters - Bed Motion	• Bedside and remote locking of bed motion • Bedside and remote monitoring of bed exit sensitivity	• Bedside locking of bed motion • Bedside and remote monitoring of bed exit sensitivity	Remote activation using Subject device.
Bed Status Parameters - Bed Exit	• Bedside and remote activation • Bedside and remote status monitoring	• Bedside activation • Bedside and remote status monitoring	Remote activation using Subject device.
Bed Status Parameters - Bed and Patient Position Monitoring	• iBed™ Watch	• iBed™ Awareness	None. iBed™ Awareness was renamed as iBed™ Watch.
Bed Status Parameters – Patient Fall Risk	• Displays assessment and score	• Not available	Subject device function only.
Bed Status Parameters – Rounding	• Displays assessment and score	• Not available.	Subject device function only.

Device Characteristic	Subject Device iBed™ Wireless with iBed™ Mobile (K202964)	Predicate Device iBed™ Wireless with iBed™ Awareness (K103536)	Differences
Bed Status Parameters – Support Surface Settings (if available)	• Remote display of assessment and score	• Not available	Subject device function only.
Bed Status Parameters – Bed Scales	• Remote display of scale information	Same	None
Installation	1. Configure bed for wireless connection to the central healthcare Delivery Organization's Information System network server. 2. Install iBed™ Mobile application from relevant mobile application stores (i.e. Apple). 3. Configure iBed™ Mobile for use.	1. Install iBed™ Locator into the room / bay. 2. Associate iBed™ Locator to the healthcare delivery organization's room / bay. Upgrade bed software (if needed). 3. Configure bed for wireless connection to the private healthcare delivery Information System network server.	Subject device requires the iBed™ Mobile application to be installed on handheld electronic device and configured to the healthcare delivery organization's protocols.
User Operation	1. The healthcare professional initially sets bed parameter settings at bedside. 2. Data is automatically sent to server and downloaded to monitoring station and Subject device.	1. The healthcare professional initially sets bed parameter settings at bedside. 2. Data is automatically sent to server and downloaded to monitoring station.	Subject device provides the ability to set, adjust, and monitor bed status parameters from remote location within the healthcare delivery organization.

Device Characteristic	Subject Device iBed™ Wireless with iBed™ Mobile (K202964)	Predicate Device iBed™ Wireless with iBed™ Awareness (K103536)	Differences
	3. The healthcare professional completes her/his review of the bed parameters at monitoring station or using the iBed™ Mobile application. Based on healthcare delivery organization (HDO) protocols, the healthcare professional may set, adjust, and/or continue monitoring bed parameters.	3. The healthcare professional completes her/his review of the bed parameters at monitoring station. 4. Healthcare provider able to monitor bed parameters from a different location within the healthcare delivery organization. 5. If adjustments are needed, the healthcare professional must be bedside to make them.	The Predicate device must have bed adjustments made at bedside and can be monitored at bedside and nurse station.
Primary Device Function	Bi-directional data transmission of specific bed parameters between HDO's central Information System software system.	One-way directional data transmission of specific bed parameters between HDO's central Information System software system.	Subject device utilizes bi-directional data communication versus the Predicate device's one-way data communication.
User Interface	The bed's footboard panel must be used to initially set bed status parameters.	Same	None
	The iBed™ Mobile application adds the following GUI screens: ● Login ● List View	Adjustments must be made at bedside.	iBed™ Mobile

Device Characteristic	Subject Device iBed™ Wireless with iBed™ Mobile (K202964)	Predicate Device iBed™ Wireless with iBed™ Awareness (K103536)	Differences
	• Room View • iBed Watch Status • Falls Tab • Rounding Tab • Skin Tab • Scale Tab		
Main System Components	• iBed™ Wireless WiFi Module (Bed) • Bi-directional iBed™ Wireless Software • iBed™ Mobile • iBed™ Watch	• iBed™ Wireless WiFi Module (Bed) • Uni-directional iBed™ Wireless Software • iBed™ Awareness	iBed™ Mobile
Wireless Communications – Data Transmission	Bi-directional data transmission: Bed to server to iBed™ Mobile to healthcare professional and then back to iBed™ Mobile then back to server then back to bed.	Uni-directional data transmission: Bed to server.	Two-way data transmission versus one-way data transmission.
Wireless Communications – WiFi Radio Module	WiFi module - IEEE 802.11 a/b/g/n/ac (bi-directional)	WiFi module - IEEE 802.11 b/g (uni-directional)	Subject device module upgraded to next generation radio.

Device Characteristic	Subject Device iBed™ Wireless with iBed™ Mobile (K202964)	Predicate Device iBed™ Wireless with iBed™ Awareness (K103536)	Differences
(Houses Data Transmission Software)			
Database	Healthcare delivery organization's central Information System software server.	Same	None

VII. NON-CLINICAL PERFORMANCE DATA

Design verification and validation testing was performed on the iBed™ Wireless with iBed™ Mobile device as a result of risk analysis and product requirements. Testing requirements included software verification, bench performance, and design validation. Software verification testing was conducted to ensure the bi-directional capability performed according to specification. Bench performance testing was conducted to ensure the Stryker Medical bed software, firmware, and iBed™ Mobile performed together according to specification.

Biocompatibility testing and non-clinical animal testing were not required to demonstrate substantial equivalence to the predicate device.

The following guidance and standards were used for performance testing:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005

- Radio-Frequency Wireless Technology in Medical Devices – Draft Guidance, August 14, 2013

- Off-The-Shelf Software Use in Medical Devices, Guidance for Industry and Food and Drug Administration Staff, September 27, 2019

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Draft Guidance, October 18, 2018

- Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices, July 11, 2016

- Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff, February 3, 2016

- ISO 14971, 2nd Edition, 2007-03-01 - Medical devices – Application of risk management to medical devices (FDA consensus standard 5-40)

- ANSI/AAMI/IEC 60601-1:2005/ (R)2012 and A1:2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD), C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text, FDA consensus standard 19-4)

- IEC 60601-1-2, Edition 4.0, 2014-02 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (FDA consensus standard 19-8)

- IEC 60601-2-52, Edition 1.0, 2009-12 - Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds [Including: Technical Corrigendum 1 (2010)] (FDA consensus standard 6-321)

- IEEE 802.11:2013 - IEEE Standard for Information technology -- Telecommunications and information exchange between systems -- Local and metropolitan area networks-Specific requirements -- Part 11: Wireless LAN Medium Access Control (MAC) and Physical Layer (PHY) Specifications

- AIM 7351731, Rev. 2.00, 2017-02-23 - Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers - An AIM Standard (FDA consensus standard 19-30)

- IEC 62304-1 Edition 1.0 2016-10 - Medical device software – Software lifecycle processes, published 4/7/2016 (FDA consensus standard 13-79)

- AAMI TIR69:2017 - Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems (FDA consensus standard 19-22)

- IEC TIR 80001-2-2, Edition 1.0 2012-07 - Application of risk management for IT-networks incorporating medical devices – Part 2-2: Guidance for the communication of medical device security needs, risks and controls (FDA consensus standard 13-42)

- IEC TIR 80001-2-8, Edition 1.0 2016-05 - Application of risk management for IT-networks incorporating medical devices – Part 2-8: Application guidance – Guidance on standards for establishing the security capabilities identified in IEC 80001-2-2 (FDA consensus standard 13-102)

- NIST SP 800-53, Revision 4 - Security and Privacy Controls for Federal Information Systems and Organizations

- IEEE C63.27 – 2017 - American National Standard for Evaluation of Wireless Coexistence (FDA consensus standard 19-29)

- RSS-247 Issue 2:2017 - Digital Transmission Systems (DTSs), Frequency Hopping Systems (FHSs) and License - Exempt Local Area Network (LE-LAN) Devices

- 47 CFR 15 Subpart C and E - Radio Frequency Devices (United States) - Licensing with Federal FCC

The following tests were conducted on iBed™ Wireless with iBed™ Mobile:

- Signal Integrity Testing
- Integration Testing: Graybox Testing
- Integration Testing: Software to Software
- Integration Testing: Software to Hardware
- Lifecycle Testing
- Power Cycle Testing
- Low Power Testing
- Max Power Consumption
- Security Testing
- WiFi Interoperability Test
- Coexistence
- Durability
- Environmental
- Static Analysis

- Power Short
- Blackbox Testing
- Performance Testing
- System Testing
- Usability Testing
- Torture Track Testing
- Drop Test
- Box and Label Chemical and Cleaning
- Roaming Test
- Targeted Vulnerability Testing
- Internal Testing
- Impact Test
- Penetration
- Input Test

VIII. CLINCAL PERFORMANCE TESTING

Clinical Studies were not required to demonstrate substantial equivalence to the predicate device.

IX. CONCLUSIONS

The iBed™ Wireless with iBed™ Mobile device is substantially equivalent to the legally marketed predicate device as the difference in the technological characteristics for accessing and ability to view or change some specific bed parameters does not raise new questions of safety and effectiveness as compared to the predicate. The iBed™ Wireless with iBed™ Mobile device has the same intended use and indications for use as the predicate device for monitoring of in-bed activity and information transmission to health care providers about patient status for patients using hospital beds in the HDO facility. The subject device does have different technological characteristics from the predicate. However these differences do not raise new questions of safety and effectiveness. Non-clinical performance data demonstrates that the subject device is substantially equivalent to the predicate.

The iBed™ Wireless with iBed™ Mobile device has been designed, tested, and confirmed to comply with recognized safety and performance standards applicable to General Healthcare facility Medical Devices. Based on the iBed™ Wireless with iBed™ Mobile's technological characteristics, completed non-clinical bench testing, and when compared with the predicate device, Stryker Medical concludes the iBed™ Wireless with iBed™ Mobile is substantially equivalent to the predicate device the iBed™ Wireless with iBed™ Awareness (K103536).