June 18, 2018

Bard Access Systems, Inc.
C.R. Bard, Inc.
Christopher Phillips
Regulatory Affairs Associate Manager
605 North 5600 West
Salt Lake City, Utah 84116

Re: K180560
Trade/Device Name: Sherlock 3CG+ Tip Confirmation System (TCS)
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS
Dated: May 18, 2018
Received: May 21, 2018

Dear Christopher 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Alan M. Stevens -S

Digitally signed by Alan M. Stevens -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300189211, cn=Alan M. Stevens -S
Date: 2018.06.18 12:51:54 -04'00'

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180560

Device Name
Sherlock 3CG+™ Tip Confirmation System (TCS)

Indications for Use *(Describe)*

The Sherlock 3CG+™ Tip Confirmation System (TCS) is indicated for navigation and positioning of central venous access devices (CVADs) of at least 2 Fr in size. The Sherlock 3CG+™ TCS provides real-time catheter tip location information by using catheter navigation technology along with the patient's cardiac electrical activity and is indicated for use as an alternative method to chest X-ray and fluoroscopy for CVAD tip placement confirmation of approaches from the superior vena cava.

In adult patients and in adolescents (greater than 12 through 21 years of age), the Sherlock 3CG+™ TCS can be used with CVADs such as peripherally inserted central catheters (PICCs), central venous catheters (CVCs), implantable ports, and hemodialysis catheters; in children (greater than 2 to 12 years of age), in infants (greater than 1 month to 2 years of age), and in neonates (from birth to 1 month of age), the Sherlock 3CG+™ TCS can be used with PICCs and with centrally inserted central catheters (CICCs). In each specific age group, the CVAD type and size must be chosen and the CVAD must be used according to the CVAD's indications and instructions for use.

Limiting but not contraindicated situations for this method are in patients where alterations of cardiac rhythm change the presentation of the P-wave as in atrial fibrillation, atrial flutter, severe tachycardia, and pacemaker driven rhythm. In such patients, who are easily identifiable prior to catheter insertion, the use of an additional method is required to confirm catheter tip location.

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.

SHERLOCK 3CG+™ Tip Confirmation System (TCS)
K180560
510(k) Summary
21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

1. Submitter Information

Bard Access Systems, Inc.
C.R. Bard, Inc.
605 North 5600 West Salt
Lake City, UT 84116
Phone: (801)522-5000
Fax: (801)522-4907

Contact Person: Christopher M. Phillips, Regulatory Affairs Associate Manager
510(k) Summary Date: June 18, 2018

2. Subject Device Name

Name of Device:	SHERLOCK 3CG+™ Tip Confirmation System (TCS)
Common or Usual Name:	SHERLOCK 3CG+™ Tip Confirmation System (TCS)
Classification Name:	Percutaneous, implanted, long-term intravascular catheter
Regulatory Class:	Class II
Regulation Number:	21 CFR 880.5970
FDA Product Code:	LJS

3. Predicate Device(s) and Reference Device(s)

Primary Predicate Device

510(k) Number:	K141634
Name of Device:	Nautilus Delta
Common or Usual Name:	Nautilus Delta
Owner/Manufacturer:	Bard Access Systems, Inc. (acquired from Romedex International SRL)
Classification Name:	Percutaneous, implanted, long-term intravascular catheter
Regulatory Class:	Class II
Regulation Number:	21 CFR 880.5970
FDA Product Code:	LJS

Secondary Predicate Device

510(k) Number:	K140345
Name of Device:	SHERLOCK 3CG™ Tip Confirmation System (TCS)
Common or Usual Name:	SHERLOCK 3CG™ Tip Confirmation System (TCS)
Owner/Manufacturer:	Bard Access Systems, Inc.
Classification Name:	Percutaneous, implanted, long-term intravascular catheter
Regulatory Class:	Class II
Regulation Number:	21 CFR 880.5970
FDA Product Code:	LJS

4. Device Description

The SHERLOCK 3CG+™ Tip Confirmation System (TCS) is designed to aid in central venous access device (CVAD) tip positioning through real-time navigation and electrocardiogram (ECG) technology. The SHERLOCK 3CG+™ TCS provides:

- Real-time catheter navigation information to the clinician via either: 1) ECG-based Computed R-Peak Navigation, or 2) Sherlock™ Magnet, a technology for tracking passive magnets (when used with SHERLOCK 3CG™ TPS Stylets); and
- Catheter tip placement confirmation via the patient's cardiac electrical activity, based upon identification of a maximum P-wave in the patient's intravascular ECG signal, with available catheter tip placement visual cues.

The subject device, SHERLOCK 3CG+™ TCS incorporates features from both of its predicate devices under a single tip confirmation system. The subject SHERLOCK 3CG+™ TCS differs from the primary predicate device (K141634) because it incorporates features from the secondary predicate device (K140345):

- Provides real-time catheter navigation information to the clinician via Sherlock™ Magnet Tracking, a technology for tracking passive magnets (when used with SHERLOCK 3CG™ TPS Stylets); and
- Includes optional catheter tip placement visual cues.

The subject SHERLOCK 3CG+™ TCS differs from the secondary predicate device (K140345) because it incorporates features from the primary predicate device (K141634):

- Provides real-time catheter navigation information to the clinician via ECG-based Computed R-Peak Navigation; and
- Includes optional R-wave highlighting.

The SHERLOCK 3CG+™ TCS includes the following components:

- SHERLOCK 3CG™ TCS Sensor
- Computing Platform
- SHERLOCK 3CG+™ TCS Mobile Medical Application running on a computing platform

The SHERLOCK 3CG+™ TCS also operates with the following legally-marketed accessories:

- NAUTILUS DELTA™ E Electrical Adaptor
- SHERLOCK 3CG™ ECG Leads (Fin Assembly)
- SHERLOCK 3CG™ TPS Stylet
- Remote
- Optional Printer(s)
- Sensor Holster (a reusable holster to hold the SHERLOCK 3CG™ TCS Sensor between uses)
- Remote Control Holder (a sterile, single use sheath to cover the Remote Control during a procedure)
- Sensor Holder (a sterile, single use sheath to cover the SHERLOCK 3CG™ TCS Sensor during a procedure)

No SHERLOCK 3CG+™ accessories or hardware components are being changed under this submission in terms of materials, sterilization processes, cleaning methods, disinfection methods, shelf life, or packaging. All accessories and hardware components are legally-marketed devices associated with the primary predicate device and/or the secondary predicate device.

5. Indications for Use

The SHERLOCK 3CG+™ Tip Confirmation System (TCS) is indicated for navigation and positioning of central venous access devices (CVADs) of at least 2 Fr in size. The SHERLOCK 3CG+™ TCS provides real-time catheter tip location information by using catheter navigation technology along with the patient's cardiac electrical activity and is indicated for use as an alternative method to chest X-ray and fluoroscopy for CVAD tip placement confirmation of approaches from the superior vena cava.

In adult patients and in adolescents (greater than 12 through 21 years of age), the SHERLOCK 3CG+™ TCS can be used with CVADs such as peripherally inserted central catheters (PICCs), central venous catheters (CVCs), implantable ports, and hemodialysis catheters; in children (greater than 2 to 12 years of age), in infants (greater than 1 month to 2 years of age), and in neonates (from birth to 1 month of age), the SHERLOCK 3CG+™ TCS can be used with PICCs and with centrally inserted central catheters (CICCs). In each specific age group, the CVAD type and size must be chosen and the CVAD must be used according to the CVAD's indications and instructions for use.

Limiting but not contraindicated situations for this method are in patients where alterations of cardiac rhythm change the presentation of the P-wave as in atrial fibrillation, atrial flutter, severe tachycardia, and pacemaker driven rhythm. In such patients, who are easily identifiable prior to catheter insertion, the use of an additional method is required to confirm catheter tip location.

6. Substantial Equivalence

Intended Use

The SHERLOCK 3CG+™ TCS and its predicate devices have the same intended use. The intended use of the SHERLOCK 3CG+™ TCS is to support navigation and tip positioning of central venous access devices. The SHERLOCK 3CG+™ TCS can be used as an alternative method to fluoroscopy and chest X-ray for central venous catheter tip placement confirmation.

Indications for Use

The SHERLOCK 3CG+™ TSC adopts the Indications for Use of its primary predicate device, with some minor changes. The Indications for Use for the subject and predicate devices are described in the table below. The differences do not change the intended use of the SHERLOCK 3CG+™ TCS when compared with the intended use of either predicate device. A summary of the differences between the Indications for Use of the subject device and the primary predicate device is included below:

1. *The central venous access device (CVAD) lower size compatibility limit has been expanded to include CVADs of at least 2 Fr in size, based upon representative nonclinical verification testing demonstrating accurate ECG signal reconstruction when a 2 Fr-compatible stylet is connected to the SHERLOCK 3CG+™ TCS.*
2. *The SHERLOCK 3CG+™ TCS Indications for Use for infants and neonates has been clarified to include the use of PICCs, based upon established clinical practice and*

upon clinical information provided in support of clearance of the primary predicate device.

3. *The phrase 'catheter navigation technology' has been added, based upon the presence of different catheter navigation technologies on the SHERLOCK 3CG+™ TCS.*
4. *The ability to use the SHERLOCK 3CG+™ TCS as an alternative to chest X-ray or fluoroscopy has been clarified to specify that the subject device may be used for CVAD tip placement confirmation of approaches from the superior vena cava, given that CVAD tip placement confirmation of alternative approaches (i.e., from the inferior vena cava) has not been qualified.*

Technological Characteristics

The subject SHERLOCK 3CG+™ TCS has the following similarities to the Nautilus Delta primary predicate device (K141634):

- Provides real-time catheter navigation information to the clinician via ECG-based Computed R-Peak Navigation, with available R-wave highlighting.
- Provides catheter tip placement confirmation via the patient's cardiac electrical activity, based upon identification of a maximum P-wave in the patient's intravascular ECG signal.

The subject SHERLOCK 3CG+™ TCS has the following similarities to the SHERLOCK 3CG™ TCS secondary predicate device (K140345):

- Provides real-time catheter navigation information to the clinician via Sherlock™ Magnet Tracking, a technology for tracking passive magnets (when used with SHERLOCK 3CG™ TPS Stylets).
- Provides catheter tip placement confirmation via the patient's cardiac electrical activity, based upon identification of a maximum P-wave in the patient's intravascular ECG signal, with available catheter tip placement visual cues.

The subject device combines features from its two legally-marketed predicate devices, which both have the same intended use: catheter navigation and final catheter tip placement confirmation.

The following table summarizes the substantial equivalence comparison of the subject device with the cited predicate devices.

Substantial Equivalence Comparison Table			
	SHERLOCK 3CG+™ Tip Confirmation System (TCS) (Subject Device)	**Nautilus Delta (Primary Predicate Device: K141634)**	**SHERLOCK 3CG™ Tip Confirmation System (TCS) (Secondary Predicate Device: K140345)**
Indications for Use	The SHERLOCK 3CG+™ Tip Confirmation System (TCS) is indicated for navigation and positioning of central venous access devices (CVADs) of at least 2 Fr in size. The SHERLOCK 3CG+™ TCS provides real-time catheter tip location information by using catheter navigation technology along with the patient's cardiac electrical activity and is indicated for use as an alternative method to chest X-ray and fluoroscopy for CVAD tip placement confirmation of approaches from the superior vena cava. In adult patients and in adolescents (greater than 12 through 21 years of age), the SHERLOCK 3CG+™ TCS can be used with CVADs such as peripherally inserted central catheters (PICCs), central venous catheters (CVCs), implantable ports, and hemodialysis catheters; in children (greater than 2 to 12 years of age), in infants (greater than 1 month to 2 years of age), and in neonates (from birth to 1 month of age), the SHERLOCK 3CG+™ TCS can be used with PICCs and with centrally inserted central catheters (CICCs). In each specific age group, the CVAD type and size must be chosen and the CVAD must be used according to the CVAD's indications and instructions for use. Limiting but not contraindicated situations for this method are in patients where alterations of cardiac rhythm change the presentation of the P-wave as in atrial fibrillation, atrial flutter, severe tachycardia, and pacemaker driven rhythm. In such patients, who are easily identifiable prior to catheter insertion, the use of an additional method is required to confirm catheter tip location.	The NAUTILUS DELTA™ Tip Confirmation System (TCS) is indicated for navigation and positioning of central venous access devices (CVADs) of at least 3 Fr in size. The NAUTILUS DELTA™ TCS provides real-time catheter tip location information by using the patient's cardiac electrical activity and is indicated for use as an alternative method to chest X-ray and fluoroscopy for CVAD tip placement confirmation. In adult patients and in adolescents (greater than 12 through 21 years of age), the NAUTILUS DELTA™ TCS can be used with CVADs such as peripherally inserted central catheters (PICCs), central venous catheters (CVCs), implantable ports, and hemodialysis catheters; in children (greater than 2 to 12 years of age), the NAUTILUS DELTA™ TCS can be used with PICCs and with centrally inserted central catheters (CICCs); in infants (greater than 1 month to 2 years of age) and in neonates (from birth to 1 month of age), the NAUTILUS DELTA™ TCS can be used with CICCs. In each specific age group, the CVAD type and size must be chosen and the CVAD must be used according to the CVAD's indications and instructions for use. Limiting but not contraindicated situations for this method are in patients where alterations of cardiac rhythm change the presentation of the P-wave as in atrial fibrillation, atrial flutter, severe tachycardia, and pacemaker driven rhythm. In such patients, who are easily identifiable prior to central venous catheter insertion, the use of an additional method is required to confirm catheter tip location.	The Sherlock 3CG™ Tip Confirmation System (TCS) is indicated for guidance and positioning of Peripherally Inserted Central Catheters (PICCs). The Sherlock 3CG™ TCS provides real-time PICC tip location information by using passive magnet tracking and the patient's cardiac electrical activity (EGG). When relying on the patient's ECG signal, the Sherlock 3CG™ TCS is indicated for use as an alternative method to chest X-ray and fluoroscopy for PICC tip placement confirmation in adult patients. Limiting but not contraindicated situations for this technique are in patients where alterations of cardiac rhythm change the presentation of the P-wave as in atrial fibrillation, atrial flutter, severe tachycardia, and pacemaker driven rhythm. In such patients, who are easily identifiable prior to catheter insertion, the use of an additional method is required to confirm PICC tip location.
Software	Mobile medical application operating on qualified operating systems and on qualified portable computing platforms	Mobile medical application operating on qualified operating systems and on qualified portable computing platforms	Standalone software application operating on qualified operating systems and on qualified portable computing platforms

Substantial Equivalence Comparison Table			
	SHERLOCK 3CG+™ Tip Confirmation System (TCS) (Subject Device)	**Nautilus Delta (Primary Predicate Device: K141634)**	**SHERLOCK 3CG™ Tip Confirmation System (TCS) (Secondary Predicate Device: K140345)**
Software: Methods for Catheter Navigation	Real-time catheter navigation via: • Sherlock™ Magnet Tracking, when used with SHERLOCK 3CG™ TPS Stylets (that are compatible with 3Fr or larger CVADs) • ECG-based Computed R-Peak Navigation when used with conductive stylets compatible with 2Fr or larger CVADs OR when using the saline column method with 3Fr or larger CVADs	Real-time catheter navigation via: • ECG-based Computed R-Peak Navigation when used with conductive stylets compatible with 3Fr or larger CVADs OR when using the saline column method with 3Fr or larger CVADs	Real-time catheter navigation via: • Sherlock™ Magnet Tracking, when used with SHERLOCK 3CG™ TPS Stylets (that are compatible with 3Fr or larger CVADs)
Software: R-wave Highlighting	Available	Available	Not available
Software: Method for Catheter Tip Placement Confirmation	Catheter tip placement confirmation via the patient's cardiac electrical activity, based upon identification of a maximum P-wave in the patient's intravascular ECG signal collected via conductive stylets compatible with 2Fr or larger CVADs OR via the saline column with 3Fr or larger CVADs	Catheter tip placement confirmation via the patient's cardiac electrical activity, based upon identification of a maximum P-wave in the patient's intravascular ECG signal collected via conductive stylets compatible with 3Fr or larger CVADs OR via the saline column with 3Fr or larger CVADs	Catheter tip placement confirmation via the patient's cardiac electrical activity, based upon identification of a maximum P-wave in the patient's intravascular ECG signal collected via a conductive stylet
Software: P-wave Highlighting	Available	Not available	Available
Software: Available Catheter Tip Placement Visual Cues	When the software detects a maximum P-wave in the patient's ECG signal and the clinician is not using ECG-based Computed R-Peak Navigation, two different visual cues are presented to the user (if selected): • The Green Diamond Indicator is displayed on the User Interface when the software detects a maximum P-wave without initial negative deflection in the patient's ECG signal • P-wave highlighting changes from yellow to green	Not available	When the software detects a maximum P-wave in the patient's ECG signal, two different visual cues are presented to the user (if selected): • The Green Diamond Indicator is displayed on the User Interface when the software detects a maximum P-wave in the patient's ECG signal • P-wave highlighting changes from yellow to green

Substantial Equivalence Comparison Table			
	SHERLOCK 3CG+™ Tip Confirmation System (TCS) (Subject Device)	**Nautilus Delta (Primary Predicate Device: K141634)**	**SHERLOCK 3CG™ Tip Confirmation System (TCS) (Secondary Predicate Device: K140345)**
Software: ECG Signals Displayed on the Graphical User Interface (GUI)	Comparative display of: • Real-time external (skin) ECG waveform • Frozen external ECG waveform (taken by the user at a desired reference point) ALONG WITH EITHER comparative display of: • Real-time intravascular ECG waveform (detected at the tip of the stylet) • Frozen intravascular ECG waveform (taken by the user at a desired reference point)s OR comparative display of: • Real-time computed ECG navigation signal • Frozen computed ECG navigation signal (taken by the user at a desired reference point)	Comparative display of: • Real-time external (skin) ECG waveform • Frozen external ECG waveform (taken by the user at a desired reference point) ALONG WITH EITHER comparative display of: • Real-time intravascular ECG waveform (detected at the tip of the stylet) • Frozen intravascular ECG waveform (taken by the user at a desired reference point) OR comparative display of: • Real-time computed ECG navigation signal • Frozen computed ECG navigation signal (taken by the user at a desired reference point)	Comparative display of: Real-time external (skin) ECG waveform • Frozen external ECG waveform (taken by the user at a desired reference point) ALONG WITH comparative display of: • Real-time intravascular ECG waveform (detected at the tip of the stylet) • Frozen intravascular ECG waveform (taken by the user at a desired reference point)
Computing Platform: Power Source	A/C power, or battery power	Battery power	A/C power, or battery power
Components	• SHERLOCK 3CG™ TCS Sensor • Computing platform • SHERLOCK 3CG+™ TCS Mobile Medical Application	• NAUTILUS DELTA™ ECG Cable • NAUTILUS DELTA™ Patient Module • Computing platform • NAUTILUS DELTA™ TCS Mobile Medical Application	• SHERLOCK 3CG™ TCS Sensor • Computing platform • SHERLOCK 3CG™ TCS Software Application
Accessories	• NAUTILUS DELTA™ E Electrical Adaptor • SHERLOCK 3CG™ ECG Leads (Fin Assembly) • SHERLOCK 3CG™ TPS Stylet • Remote • Optional Printer(s) • Sensor Holster • Remote Control Holder • Sensor Holder	• NAUTILUS DELTA™ E Electrical Adaptor • SHERLOCK 3CG™ TPS Stylet • Remote • Optional Printer(s) • Patient Module Holster • Remote Control Holder • Patient Module Holder	• SHERLOCK 3CG™ ECG Leads (Fin Assembly) • SHERLOCK 3CG™ TPS Stylet • Remote • Optional Printer(s) • Sensor Holster • Remote Control Holder • Sensor Holder

7. Performance Data

Testing verifying the performance requirements of the subject device was conducted and is included in this premarket notification, the results of which support substantial equivalence. All subject device accessories and hardware components are legally marketed with the primary and secondary predicate devices. The following table lists subject device design requirements and corresponding nonclinical tests submitted, referenced, or relied on in the premarket notification for a determination of substantial equivalence. All tests listed in the following table are from this submission only for the purpose of verifying changes to the device. Previously submitted design verification and validation data from K141634 and K140345 were relied on where appropriate.

Design requirements and corresponding nonclinical tests	
• User needs	Sherlock 3CG TCS Standalone Software Verification
	Magnet Tracking Accuracy
• Physical characteristics • Electrical, electronic, and radiation characteristics • Thermal characteristics • Mechanical characteristics	Sherlock 3CG TCS Standalone Electrical Safety and EMC - IEC 60601-1 Edition 3.1
• Operating environment	Temperature and Humidity Testing
• Labeling characteristics	Sherlock 3CG TCS Standalone Electrical Safety and EMC - IEC 60601-1 Edition 3.1
	Temperature and Humidity Testing
• Equipment and device interfaces and mounting • Minimum requirements for computing platform • Usability requirements	Sherlock 3CG TCS Standalone Software Verification
	SherlockShell Software Verification
• Operating requirements	Magnet Tracking Accuracy
	Sherlock 3CG TCS Standalone Software Verification
• Software requirements	Sherlock 3CG TCS Standalone Software Verification
	SherlockShell Software Verification
	Magnet Tracking Accuracy
	Sherlock 3CG TCS System Verification
• Dimensional characteristics • Chemical characteristics • Biological and biocompatibility characteristics • Packaging characteristics	No changes to any dimensional characteristics, chemical characteristics, biological and biocompatibility characteristics, or packaging characteristics under this premarket notification when compared with the primary predicate device and/or secondary predicate device. Previously submitted biocompatibility data submitted under K140345 verify compatibility of the device materials.

The following guidance documents and standards were used to determine appropriate methods for evaluating the performance of the subject device:

- FDA Guidance – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- FDA Guidance – Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- FDA Guidance – Postmarket Management of Cybersecurity in Medical Devices
- FDA Guidance - Applying Human Factors And Usability Engineering To Medical Devices
- AAMI TIR 57:2016, Principles For Medical Device Security – Risk Management
- AAMI / ANSI EC12:2000/I2010, Disposable ECG Electrodes
- AAMI / ANSI HE75:2009/(R)2013, Human Factors Engineering - Design Of Medical Devices
- ISO 14971 Second Edition 2007-03-01, Medical Devices - Application Of Risk Management To Medical Devices
- AAMI / ANSI / IEC 62366:2007/(R)2013, Medical Devices - Application Of Usability Engineering To Medical Devices
- IEC 60601-1 INT 3 C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2 Edition 3: 2007-03, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
- IEC 62133 Edition 2.0 2012-12 Secondary Cells And Batteries Containing Alkaline Or Other Non-Acid Electrolytes - Safety Requirements For Portable Sealed Secondary Cells, And For Batteries Made From Them, For Use In Portable Applications
- IEC 62304 Edition 1.1 2015-06, Medical Device Software - Software Life Cycle Processes
- ISO 15223-1 Third Edition 2016-11-01 Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements

The subject device, SHERLOCK 3CG+™ TCS, met all predetermined acceptance criteria derived from the above listed tests and demonstrated substantially equivalent performance as compared to the cited primary and secondary predicate devices.

8. Clinical Performance Data

No new human clinical data was provided to support substantial equivalence. Design validation data supporting device performance was provided under K141634 and K140345.

9. Conclusion Regarding Substantial Equivalence

The subject device, SHERLOCK 3CG+™ TCS, has the same intended use and the same fundamental scientific technology as the primary and secondary predicate devices. The subject device has the same Intended Use, similar Indications for Use and incorporates the same fundamental technology as the legally marketed predicate devices to which it was compared. Based on Intended Use, technological characteristics, and performance testing, it can be

concluded that the subject device, SHERLOCK 3CG+™ TCS, is substantially equivalent to both the primary predicate device and the secondary predicate device.