



Food and Drug Administration  
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January 12, 2016

Richard Wolf Medical Instruments Corporation  
Ms. Lisa Williams  
Regulatory Affairs Assistant  
353 Corporate Woods Parkway  
Vernon Hills, Illinois 60061

Re: K151282

Trade/Device Name: core nova Complete Operating Room Endoscopy  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: Class II  
Product Code: ODA  
Dated: December 11, 2015  
Received: December 15, 2015

Dear Ms. Williams:

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" (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 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,

**Jennifer R. Stevenson -S**

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K151282

Device Name

core nova Complete Operating Room Endoscopy

Indications for Use (Describe)

Core.nova (core.browser, core.connect with driver, IR Transceiver, core.media, and core.portal) are components used for the central control of integrated medical devices and accessories in one central location within the operating room. In particular core.nova is used for the control of connected compatible OR equipment, like OR-lamp, OR-camera, OR-table, insufflator, or video- and documentation system intended for diagnostic and therapeutic medical conditions. The connected devices (Richard Wolf or third party) can be controlled by control terminals (with touch screen), or the control mechanism on actual device.

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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## 5. 510(k) Summary

|  |   |  |                             |
|--|---|--|-----------------------------|
| <b>Submitter:</b>  |   | Date of Preparation:<br>May 01, 2015 Revised Jan. 07, 2016   |                             |
| Company / Institution name:<br><b>RICHARD WOLF MEDICAL INSTRUMENTS CORP.</b> |   | FDA establishment registration number: 14 184 79   |                             |
| Division name (if applicable):<br>N.A.                                       |   | Phone number (include area code):<br>( 847 ) 913 1113  |                             |
| Street address:<br>353 Corporate Woods Parkway                               |   | FAX number (include area code):<br>( 847 ) 913 0924  |                             |
| City:<br>Vernon Hills  | State/Province:<br>Illinois                         | Country:<br>USA  | ZIP / Postal Code:<br>60061 |
| Contact name:<br>Lisa Williams   |   |  |                             |
| Contact title:<br>Regulatory Affairs Assistant                               |   |  |                             |
| <b>Parent Company:</b>   |   |  |                             |
| Company / Institution name:<br><b>Richard Wolf GmbH</b>                      |   | FDA establishment registration number: 96 111 02   |                             |
| Street address:<br>Pforzheimer Str. 32                                       |   |  |                             |
| City:<br>Knittlingen   | State/Province:<br>Baden-Württemberg                | Country:<br>Germany  | ZIP / Postal Code:<br>75438 |
| <b>Product Information:</b>  |   |  |                             |
| Trade name:<br><i>core nova</i> Complete Operating Room Endoscopy            |   | Model numbers:<br>5592201, 5592501, 5592504, 55926xx, 5593001,<br>and their accessories                        |                             |
| Common name:<br>Endoscopic Central Control Unit                              |   | Classification name:<br>876.1500; ODA Endoscopic Central Control Unit,<br>Endoscope and accessories. Class II. |                             |
| <b>Information on devices to which substantial equivalence is claimed:</b>   |   |  |                             |
| 510(k)<br>Number   | Trade or proprietary or model name                  | Manufacturer   |                             |
| 1 K020255  | 1 RIWO NET Operating Control System<br>Model # 5590 | 1 Richard Wolf   |                             |

## 1.0 Description

The *core nova* (complete operating room endoscopy nova) by Richard Wolf is a network-based integrated operating room accessory that provides central control to various Richard Wolf devices and third party devices. This control allows the user to control device settings from the sterile area.

Richard Wolf's *core nova* is comprised of *core.browser*, *core.connect* with driver, IR Transceiver, an optional *core.media*, and an optional server *core.portal*.

- The software *core.browser* is used to control an OR system in conjunction with *core nova*.
- The *core.connect* module is used for the connection of external medical devices to *core nova* and allows the triggering of predefined functions.
- In conjunction with the *core.connect* hardware, the product-specific drivers are used for remote-controlling the specified devices within *core nova*.
- The IR Transceiver infrared module serves to connect external medical devices equipped with an infrared interface to *core nova* in order to control predefined functions.
- The *core.media* device is designed for distributing and recording video signals and video data within *core nova*.
- The *core.portal* is designed for exchange of information with hospital information systems (HIS), image archiving (PACS) and billing systems.

Devices which are integrated into the Richard Wolf *core nova* can be controlled via the *core nova* centrally from one or more work stations in the operating room via software installed on a control terminal. The connected devices can be controlled via the ***core nova***, using: control terminals with touch screens, user presets, as well as the control options on the connected devices themselves.

Devices included in ***core nova*** devices are reusable and do not require sterilization because there is no direct / in-direct patient contact. For device operation, a short contact of the operator with control terminal interface (touchscreen) will occur. Methods of cleaning and disinfection are detailed in the Instruction for Use.

Core nova use is exclusively intended for use by medical experts and may only be used by adequately qualified and trained medial doctors.

## 2.0 Indications for Use

*Core.nova* (*core.browser*, *core.connect* with driver, IR Transceiver, *core.media*, and *core.portal*) are components used for the central control of integrated medical devices and accessories in one central location within the operating room.

In particular *core.nova* is used for the control of connected compatible OR equipment, like OR-lamp, OR-camera, OR-table, insufflators, or video- and documentation system intended for diagnostic and therapeutic medical conditions. The connected devices (Richard Wolf or third party) can be controlled by control terminals (with touch screen), or the control mechanism on actual device.

**WARNING!** The safety and efficacy of the use of this system has not been evaluated along with the use of a robotic assisted surgical device in the OR environment.

### 3.0 Comparison of Technological Characteristics with the Predicate Devices

| Manufacturer   | Richard Wolf   | Richard Wolf                                     | SE Decision                      |
|--|--|--|----------------------------------|
| Trade Name   | <i>Core Nova</i>   | <b>RIWO-NET</b>                                  | N/A                              |
| 510(k) Number  |  | K020255  | N/A                              |
| Product Code   | ODA  | KOG  | Equivalent                       |
| Regulation Number  | 876.1500   | 876.1500   | Equivalent                       |
| Regulation Name  | Endoscopic Central Control Unit                                | Endoscope and/or Accessories                     | Equivalent                       |
| Indications for Use                                      | Central control of devices in the operating room               | Central control of devices in the operating room | Equivalent                       |
| Connection type  | LAN/Ethernet   | CAN-Bus  | Equivalent,<br>See SE Discussion |
| Connection with foreign devices                          | interface box <i>core.connect</i> 5592501 with drivers 55926xx | individual CAN interfaces 5590.8xx               | Equivalent,<br>See SE Discussion |
| Material   | Metal & plastics   | Metal & plastics                                 | Equivalent                       |
| AC Powered   | yes  | yes  | Equivalent                       |
| Electrical Safety Testing                                | IEC 60601-1<br>IEC601-1-2                                      | IEC 60601-1<br>IEC601-1-2                        | Equivalent                       |
| Show centrally operating parameters of connected devices | yes  | yes  | Equivalent                       |
| Show centrally warnings of connected devices             | yes  | yes  | Equivalent                       |
| Designed for use in ceiling supply units or video cart   | yes  | yes  | Equivalent                       |
| media management   | <i>core.media</i> , inside the operating room                  | outside operating room                           | Equivalent                       |
| Principle of operation                                   | Multi-master communication                                     | only one master possible                         | Equivalent                       |

The main difference between predicate RIWO-NET and new *core nova* by Richard Wolf is the interconnection between the components, made via LAN (Ethernet) interface at the new *core nova* instead via CAN-bus interface before. The functionality is equivalent.

For the connection of equipments by foreign manufacturers interface boxes are also used in these systems, which are equivalent to Richard Wolf's interface box *core.connect* 5592501.

The differences between the above comparisons products and the *core nova* are mainly related to the following aspects:

- The presentation mode at the appropriate monitor(s)
- The kinds of functions for the remote control of the device models to be connected
- The transfer type between the OR devices and the control computer

### 4.0 Substantial Equivalence Discussion

The submitted devices pose the same type of questions about safety or effectiveness as the compared devices and the new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing 510(k)-cleared devices sold by Richard Wolf (K020255).

## 5.0 Performance Data

### Biocompatibility testing

There is no direct or indirect patient contact with core nova, Biocompatibility testing is not applicable.

### Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the *core nova* devices

The components of *core nova* comply with the standards:

- IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007): Medical electrical equipment Part 1: General requirements for basic safety and essential performance (3<sup>rd</sup> edition)
- ANSI/AAMI ES60601-1 Medical electrical equipment- Part I: General requirements for basic safety and essential performance, C1: 2009, Amendment 2: 2010.
- 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
- EN 61000-3-2/ EN 61000-3-3 Electromagnetic compatibility (harmonics/ flicker) for limit class: A

### Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for these devices was considered as a "minor" level of concern, but components that control devices with a "moderate" level of concern were considered as a "moderate" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

### Animal Study or Clinical Studies

Preclinical laboratory studies, tissue or animal testing were not performed.

## 7.0 Conclusions

*Core nova* has the same Indications for use as the predicate devices. The different technological characteristics are demonstrated to be substantially equivalent to the predicate devices by Richard Wolf, and the *core nova* components does not raise different questions regarding its safety and effectiveness as compared to the referenced predicate device.

Core nova devices were non-clinically tested to determine the safety and efficacy under the indications for use and meet aforementioned safety standards, same as the predicate device.

For these reasons, The Richard Wolf core nova is substantially equivalent to the existing 510(k) cleared devices sold by Richard Wolf (K020255).