



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Integra NeuroCare LLC
Ms. Nancy A. Mathewson, Esq.
Manager, Regulatory Affairs
5955 Pacific Center Boulevard
San Diego, CA 92121

JUL 27 2015

Re: K992006
Trade/Device Name: Neuroview® Instrument Holder (Model 300-33)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCV, GCJ
Dated (Date on orig SE ltr): June 14, 1999
Received (Date on orig SE ltr): June 15, 1999

Dear Ms. Mathewson,

This letter corrects our substantially equivalent letter of August 17, 1999.

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

Indications

510(k) Number: K 992006

Device Name: Neuroview® Instrument Holder (Model: 300-33)

Indications for Use:

Neuroview® Instrument Holder (Model: 300-33) is intended for use in holding Neuro Navigational Neuroview Endoscopes in a desired position over the patient during diagnostic and therapeutic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Or

Over-the-Counter Use

Optional Format 1-2-96)

Michael L. Puzone for JDS
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 992006

AUG 17 1999

 **INTEGRA NEURO CARE LLC**

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Summary of Safety and Effectiveness
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K 992006

"NEUROVIEW® INSTRUMENT HOLDER (MODEL 300-33)"

SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's name and address:

Integra NeuroCare LLC
5955 Pacific Center Blvd.
San Diego, CA 92121-4309

Contact person and telephone number:

Nancy A. Mathewson
Manager
Regulatory Affairs
(858) 455-1115 X 185

Manufacturing Facility:

Integra NeuroCare LLC
5955 Pacific Center Blvd.
San Diego, CA 92121-4309

Establishment Registration Number: 2023988

Date Summary was prepared: June 11, 1999

Name of the device:

Proprietary Name: Neuroview® Instrument Holder (Model 300-33)
Common Name: Endoscope Holder
Classification Name: Neurological Endoscope (21 CFR 882.1480)

Substantial Equivalence: The Neuroview® Instrument Holder (Model 300-33) is substantially equivalent to the following currently marketed instruments or endoscope holders:

- KSEA Endoscope Holder (K990334)
- Codman Rigid and Steerable Endoscope Holders (K945572)
- Leonard Arm-Support Arm-Endoscope Accessory (K951854)

Device Description: The Neuroview® Instrument Holder, Model 300-33, is a reusable, stainless steel accessory used to hold currently marketed Neuro Navigational Endoscopes. The holder consists of a rail clamp, adjustable stainless steel rods, toggle clamps, and an instrument clamp.

This Instrument Holder, as well as the predicate devices, includes a one-piece design that is completely stable when used to position an instrument. The arms contain adjustable stainless steel clamps and holders that will adapt to any operating room table and hold any Neuro Navigational Endoscope. The holder can be positioned over the patient and locked into place to facilitate accurate Endoscope manipulation and instrument passage. The Instrument Holder, as well as the predicates accessory devices, is sold non-sterile and autoclavable for rapid operating room preparation.

This Instrument Holder is intended to hold the Neuroview Endoscope in place. It has no direct contact with the patient. The only important performance aspect of the Instrument Holder is that it maintains its position once it has been positioned and tightened in place.

Statement of intended use: The Neuroview® Instrument Holder (Model 300-33) is intended for use in holding Neuro Navigational Neuroview Endoscopes in a desired position over the patient during diagnostic and therapeutic procedures.

Comparison of technological characteristics to predicate devices: A feature comparison chart between Neuroview Instrument Holder (Model 300-33) and the currently marketed predicates KSEA Endoscope Holder, Codman® Rigid and Steerable Endoscope Holders and Leonard Arm-Support Arm-Endoscope Accessory is presented in Table 1.

Safety

None of the Neuroview® Instrument Holder (Model 300-33) components have patient, blood, and/or fluid contact. The Instrument Holder is composed of stainless steel materials that are widely used in other instrument and scope holders.

Table 1: Substantial Equivalence Comparison Chart

Parameter	Neuroview® Instrument Holder (300-33)	KSEA Endoscope Holder	Codman® Rigid and Steerable Endoscope Holders	Leonard Arm-Support Arm-Endoscopic Accessory
Manufacturer	Integra NeuroCare LLC	Karl Storz Endoscopy-America, Inc.,	Johnson & Johnson Professionals, Inc	Leonard Medical, Inc
Intended Use	Rigidly Affix Endoscopes	Rigidly Affix Endoscopes	Rigidly Affix Endoscopes	Rigidly Affix Endoscopes
Materials	Stainless Steel	Stainless Steel and Anodized Aluminum	Stainless Steel and Silicone Rubber	Stainless Steel
Means of Mounting	Table Mounted	Table Mounted	Table Mounted	Table Mounted
Adjustable	Yes	Yes	Yes	Yes
Possible to sterilize	Yes	Yes	Yes	Yes