K132039

FEB 21 2014

JEDMED
An Employee-Owned Company
5416 JEDMED COURT • ST. LOUIS, MO 63129 PHONE: (314) 845-3770 •FAX: (314) 845-3771
E-MAIL: INFO@JEDMED.COM WEB SITE: www.jedmed.com

5. 510(k) - Summary

Submitter:	JEDMED Instrument Company 5416 JEDMED Court St. Louis, MO 63129
Contact:	Craig Parks Regulatory Affairs /QA Manager Phone: 314-845-3770 Email: craigp@jedmed.com
Date:	July1, 2013
Name of Device:	Laryngo-Nasopharyngoscope EF-N, EF-N Slim
Common Name:	Naso-pharyngo-laryngo-flexible scope
Classification Name of Device:	Laryngo, Nasopharyngoscope a) product code: EQN b) regulation number: 874.4760
Legally Marketed Device to which Equivalence is Claimed:	Flexible nasopharyngo-laryngoscope and flexible bronchoscope Richard Wolf Medical Instruments Corp. (Premarket notification K992526)
Description:	This flexible scope is designed with the insertion tube with its bendable distal tip, the handle, the eyepiece and the focus ring. The handle incorporates the control lever to bend the distal tip and the connectors for the leakage tester and the fiber optic light-guide cable.
Indications for Use:	JEDMED's Ergo-Flex EF-N and EF-N Slim Laryngo-Nasopharyngoscopes are intended to examine the larynx, nasal cavity and nasal pharynx. They are used between the upper respiratory tracts of the nasal passage and the vocal cords.

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Technological Characteristics in Comparison to Predicate Device

	SE Device	**Predicate Device**
	Jedmed EF-N and EF-N Slim	**Richard Wolf Device**
Name	Laryngo, Nasopharyngoscope flexible	Flexible nasopharyngo-laryngoscope and flexible bronchoscope, Richard Wolf Medical Instruments Corp.
Identification	EF-N EF-N Slim	7222, 7223, 7224, 7265, 7325, 7330
Performance specification	Laryngo, Nasopharyngoscope	Nasopharyngoscope
Sheath diameter	2.8 and 3.4mm	3.5 mm
Working length	320 mm	300 mm
Bending angle		
Up	130°	130°
Down	130°	130°
Bending radius	8 mm	
Optical system		
Field of view	80°	95°
Depth of field	1 - 50 mm	3 – 50 mm
Weight	230 g(8 oz)	
Forceps Channel Diameter	N/A	1.1 mm

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	SE Device	**Predicate Device**
	Jedmed EF-N and EF-N Slim	**Richard Wolf Device**
Appearance, shape		
Control lever	Handling by turning, rotation axis across to longitudinal axis of the endoscope; Milled of aluminium, anodized (for mechanical resistance), parylene coated (for chemical resistance)	Handling by turning, rotation axis across to longitudinal axis of the endoscope; Milled of aluminium, black coated
Light guide connector	Compatible to ACMI, Richard Wolf and Storz light guide cable; Manufactured of stainless steel	Compatible to Richard Wolf light guide cable; Manufactured of stainless steel
Leak tester connector	XION-standard; Manufactured of plastic	Richard Wolf-standard; Manufactured of stainless steel
Biopsy channel entry	N/A	ISO594-2.2(Luer-Lock-innercone); Manufactured of stainless steel
Eyepiece	DIN 58105 (Medical endoscopes); Manufactured of medical grade plastics	DIN 58105 (Medical endoscopes); Manufactured of medical grade plastics
Body cover	Manufactured of medical grade silicone	Milled / drilled of aluminium, black coated
Suction valves (bronchoscope only)	N/A	Richard Wolf construction, cleanable by removing; Manufactured of stainless steel
Focus ring	Handling by turning, rotation axis parallel to longitudinal axis of the endoscope; Manufactured of medical grade plastics	Handling by turning, rotation axis parallel to longitudinal axis of the endoscope; Manufactured of medical grade plastics

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Similarities to predicate device: The submitted devices are equivalent to the flexible endoscopes referred to in K992526 *flexible nasopharyngo-laryngoscope and flexible bronchoscope*. The fiberscopes in the submission use the same basic design and device material as submitted in K992526.

Differences to predicate device: There are only differences regarding diameters and lengths of the insertion tube and the outer appearance and shaping of the shell parts and control elements.

Reprocessing:
Cleaning Instructions were validated using a manual cleaning process incorporating an enzymatic detergent. The following documents were referenced during the validation:

"Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices", ANSI/AAMI ST81:2004/(R) 2010

AAMI TIR No. 12:2010, "Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers".

AAMI TIR No. 30:2011; "A compendium of processes, materials, test methods and acceptance criteria for cleaning reusable medical devices.

"Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices"; ISO 17664:2004(E)

"Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guide"; Office of Device Evaluation; April 1996.

Disinfection instructions were validated using Cidex 2.4 and Cidex OPA and were tested by Geneva Test Laboratory and met all the criteria for acceptance for efficacy and material compatibility. The scope was submitted to the Steris System 1E test program for disinfecting validation and met all the criteria for efficacy and material compatibility.

Biocompatibility testing was performed according to ISO10993-1 ISO10993-5 ISO 10993-10 and no relevant cytotoxicity effects were found for direct and indirect contact. This test used the whole endoscope sheath which had already been put thru all the normal manufacturing processes.

Performance bench testing consisted of:

Temperature testing for patient and user safety. Temperature was tested at (4) different test sites using calibrated Fluke Digital Multimeter with temperature sensing module with a 50w Metal Halide Bulb, a 50w LED bulb and a 150w Halogen bulb. Tests results showed the temperature was below the 41 degree C as required byIEC60601-2-18 Part 2-18 section 201.11.

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Life cycle and angulation testing:

The angulation function was cycled a minimum of 50,000 cycles to determine that the scope would pass the minimum requirement of 26,000 cycles which could be 2 years use or more depending on the practice. All of the tested scopes met the requirement. The 130 degree angulation was still in tolerance after 30,000 cycles.

Conclusion:

The submitted devices pose the same type of questions about safety and effectiveness as the compared devices. The new technological characteristics have no influence on safety or effectiveness. The submitted devices are substantially equivalent to the 510(k) devices sold by Richard Wolf Medical Instruments Corp.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 21, 2014

Jedmed Instrument Company
Mr. Craig Parks
Regulatory Affairs/QA Manager
5416 JEDMED Court
St. Louis, MO 63129

Re: K132039
Trade/Device Name: Laryngo-Nasopharyngoscope EF-N, EF-N Slim
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EQN
Dated: January 21, 2014
Received: January 23, 2014

Dear Mr. Parks:

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,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132039

Device Name: Laryngo-Nasopharyngoscope EF-N and EF-N Slim

Indications for Use:

JEDMED's Ergo-Flex EF-N and EF-N Slim Laryngo-Nasopharyngoscopes are intended to examine the larynx, nasal cavity and nasal pharynx.
They are used between the upper respiratory tracts of the nasal passage and the vocal cords.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

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