K070580

XiON medical

6 510(k) - Summary

JUN 13 2007

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Contact:	Alexander Kliem Email akliem@xion-medical.com
Date:	05/11/2007
Name of Device:	Nasopharyngoscope EF-N, EF-NS, EF-N Slim, EF-N 14, EF-N 14 S
Common Name:	Naso-pharyngo-laryngo-fiberscope
Classification Name of Device:	Nasopharyngoscope a) product code: EOB 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:	Flexible nasopharyngoscopes with or without a working channel are built of 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 fibre-optic light-guide cable.
Indications for Use:	Nasopharyngoscopes are intended to examine or treat the nasal cavity and nasal pharynx. They are used between the upper respiratory tracts of the nasal passage and the vocal chords. They allow the recognition of anomalies in the tissue of the accessible organs. The EF-N 14 and EF-N 14S models with their working channel allow the insertion of an instrument to carry out a biopsy.

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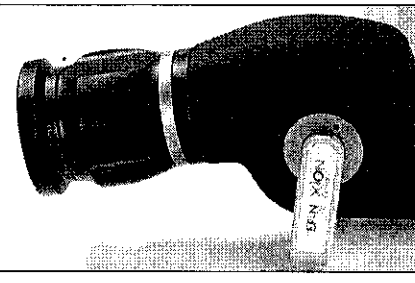
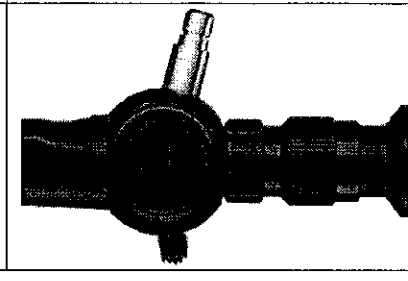
Technological Characteristics in Comparison to Predicate Device

	SE Device		**Predicate Device**
	XION Device		**Richard Wolf Device**
Name	Nasopharyngoscope (flexible or rigid)		Flexible nasopharyngo-laryngoscope and flexible bronchoscope, Richard Wolf Medical Instruments Corp.
Identification	EF-N EF-NS EF-N Slim EF-N14 EF-N14S	130 400 034 130 400 134 130 400 028 130 414 040 130 414 140	7222, 7223, 7224, 7265, 7325, 7330
Performance specification	Nasopharyngoscope		Nasopharyngoscope
Sheath diameter	2.8 - 4.1 mm		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 – 320 g		
Forceps channel diameter	1.4 mm		1.1 mm

	SE Device	Predicate Device
	XION Device	**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 stainless steel	Richard Wolf-standard; Manufactured of stainless steel
Biopsy channel entry	Compatible to FUJINON; Manufactured of stainless steel	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)	XION construction, cleanable by removing; Manufactured of stainless steel, PTFE and medical grade silicone	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
Labelling		

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. Some flexible nasopharyngoscopes have a fixed light cable instead of a removable one; some of them have a working channel.
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.

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
9200 Corporate Boulevard
Rockville MD 20850

Xion GmbH
c/o Alexander Kliem
Quality Management
Pankstraße 8-10
D-13127 Berlin
Germany

JUN 13 2007

Re: K070580
Trade/Device Name: Nasophyngoscope
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOB
Dated: May 11, 2007
Received: May 14, 2007

Dear Mr. Kliem:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M B Eydelman, MD

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

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5 Indications for Use

510(k) Number (if known):

Device Name: Nasopharyngoscope

Indications for Use: Nasopharyngoscopes are intended to examine or treat the nasal cavity and nasal pharynx. They are used between the upper respiratory tracts of the nasal passage and the vocal chords.
They allow the recognition of anomalies in the tissue of the accessible organs. The EF-N 14 and EF-N 14S models with their working channel allow the insertion of an instrument to carry out a biopsy.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K070580

Prescription Use X
(Per 21 CFR 801.109)