510(K) Summary

General Information

Preparation Date:	June 23, 2017
Owner's Name:	National Advanced Endoscopy Devices, Inc. Registration: 9027397
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Subject Device Name:	AED Sinuscope
Trade Name	AED Sinuscope
Common/Usual Name:	Sinuscope
Classification Name:	EOB- Nasopharyngoscope (flexible or rigid) and accessories 21 CFR 874.4760; Class II
Predicate Device Name:	Schoelly Sinuscope
Trade Name:	Schoelly Sinuscope
Common/Usual Name:	Sinuscope
Classification Name:	EOB- Nasopharyngoscope (flexible or rigid) and accessories 21 CFR 874.4760; Class II
Premarket Notification:	K142249, Schoelly Fiberoptic GmbH, SE date January 27, 2015

Device Description:

5700 Series AED Sinuscopes

5700A AED Sinuscope
4.0mm diameter, 0^0 Angle of View, 175mm working length

5700AXS AED Sinuscope
4.0mm diameter, 0^0 Angle of View, 50mm working length

5700B AED Sinuscope
4.0mm diameter, 30^0 Angle of View, 175mm working length

5700C AED Sinuscope
4.0mm diameter, 70^0 Angle of View, 175mm working length

5700F AED Sinuscope
4.0mm diameter, 45^0 Angle of View, 175mm working length

5727 Series AED Sinuscopes

5727A AED Sinuscope
2.7mm diameter, 0^0 Angle of View, 175mm working length

5727AX AED Sinuscope
2.7mm diameter, 0^0 Angle of View, 100mm working length

5727AXS AED Sinuscope
2.7mm diameter, 0^0 Angle of View, 50mm working length

5727BAED Sinuscope
2.7mm diameter, 30^0 Angle of View, 175mm working length

5727BS AED Sinuscope
2.7mm diameter, 30^0 Angle of View, 100mm working length

8800 Series AED Sinuscopes

8800A AED Sinuscope
4.0mm diameter, 0^0 Angle of View, 175mm working length

8800AXS AED Sinuscope
4.0mm diameter, 0^0 Angle of View, 50mm working length

8800BAED Sinuscope
4.0mm diameter, 30^0 Angle of View, 175mm working length
8800CAED Sinuscope
4.0mm diameter, 70^0 Angle of View, 175mm working length

8800F AED Sinuscope
4.0mm diameter, 45^0 Angle of View, 175mm working length

8827 Series AED Sinuscopes

8827A AED Sinuscope
2.7mm diameter, 0^0 Angle of View, 175mm working length

8827AX AED Sinuscope
2.7mm diameter, 0^0 Angle of View, 100mm working length

8827AXS AED Sinuscope
2.7mm diameter, 0^0 Angle of View, 50mm working length

8827BAED Sinuscope
2.7mm diameter, 30^0 Angle of View, 175mm working length

8827BS AED Sinuscope
2.7mm diameter, 30^0 Angle of View, 100mm working length

The AED Sinuscope is a reusable rod lens sinuscope consisting of an eyepiece lens and a light post connection for fiber optic light cables. A shaft composed of surgical grade stainless steel encloses the glass rod-lens system and a built-in fiber optic light carrier made of glass/acrylic. The light post body is also comprised of surgical stainless steel. The eyepiece is made from Ultem.

AED Sinuscopes are manufactured in multiple configurations that differ in insertion tube outer diameter and working length and with respect to optical parameters (direction of view, field of view).

The AED Sinuscope is reusable and provided non-sterile. It must be cleaned and sterilized prior to use.

Technological Characteristics

To view the sinus and nasal passages the distal end of the sinuscope with a light source attached is passed into a nasal passage. Images are transmitted to the eyepiece which is typically attached to a camera so the images received through the sinuscope can be displayed on a video screen.

Technical parameters of the AED Sinuscope are characterized by the optical view – Direction of View (0° - 70°) and the Field of View (70°). The AED Sinuscopes are available in two different lengths for the insertion tube: 4mm diameter and 2.7mm diameters with working lengths that vary from 50mm, 100mm and 175mm.

The AED Sinuscope differs from the predicate device Schoelly Sinuscope (K142249):

- The Schoelly Sinuscope comes in a 2.0mm as well as 2.7mm and 4.0mm diameters. The AED Sinuscope comes in 2.7mm and 4.0mm diameters.

- The Schoelly Sinuscope comes in 110mm, 175mm and 187mm working lengths. The AED Sinuscope comes in 50mm, 100mm and 175mm working lengths.

The different diameters and workings lengths do not change the same basic design or use of the AED Sinuscope. The same basic mechanical design, operating principles and indications for use are the same for both devices.

A detailed comparison of the technological characteristics with the predicate device is shown in the table below:

Technological Characteristics of the Proposed Device and the Predicate Device

Attribute	Proposed Device (current Submission)	Predicate Device K142249
Light Transmission	Fiberoptics	Fiberoptics
Light Source	External, connected via light post to light guide connector	External, connected via light post to light guide connector
Image Transmission	Rigid Rod Lens	Rigid Rod Lens
Diameter	4mm, 2.7mm	4mm, 2.7mm, 2.0mm
Direction of View	0^0 - 70^0	0^0 - 70^0
Field of View	70^0	80^0 - 100°
Image Display	Camera/monitor connected via the eyepiece of the sinuscope	Camera/monitor connected via the eyepiece of the sinuscope
Working Length	50mm, 100mm, 175mm	110mm, 175mm, 187mm
Working Channel	None	None
Single Use/Reusable	Reusable	Reusable
Reprocessing	Cleaning, sterilization (steam)	Cleaning, sterilization (steam, STERRAD®)
Materials		
Insertion Tube (outer surface)	stainless steel	stainless steel
Insertion Part (distal surface)	stainless steel, glass	stainless steel, glass
Fiberoptics	glass/acrylic	glass/acrylic
Lens bonding	epoxy	epoxy
Temperature Testing	IEC 60601-2-18 compliant	IEC 60601-2-18 complaint
Packaging	Case with foam insert	Case with foam insert

Indications for Use

The AED Sinuscope is intended for use in otolaryngology and Head and Neck procedures, including rhinology, and endoscopic plastic and reconstructive surgery.

Non-clinical Performance Testing

Temperature testing: The device was measured for surface temperatures at various locations over time and found to meet the requirements specified in IEC 60601-2-18: Medical Electrical Equipment - Part 2: Particular Requirements For The Basic Safety And Essential Performance Of Endoscopic Equipment. Edition 3.0 2009-08

Optical parameter testing: The device was tested for all relevant optical parameters and found to meet the minimum requirements defined in internal specifications and as specified in the ISO 8600-3:1997 and ISO 8600-3: Amendment 1: 2003 standards (field of view, direction of view).

Reprocessing

The AED Sinuscope is the subject of completed reprocessing validations including manual cleaning and steam sterilization.

The cleaning study has been performed in accordance with AAMI TIR12:2010 (Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers), AAMI TIR30:2011 (A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable devices) and FDA Guideline on General Principles of Process Validation, January 2011, Rev 1.

The sterilization study has been performed in accordance with ISO 14937:2009 (Sterilization of health care products - General requirements for characterization of sterilizing agent and the development, validation and routine control of a sterilization process for medical devices), ANSI/AAMI/ISO 17665-1:2006 (Sterilization of health care products – Moist heat - Requirements for the development, validation and routine control of sterilization process for medical devices),AAMI TIR 12:2010 (Designing, testing and labeling reusable medical devices for reprocessing in health care facilities) and ISO 17665-2:2009 (Sterilization of health care products – Moist heat – Part 2: Guidance of the application of ISO 17665-1).

Conclusion

The AED Sinuscope meets all the pre-determined acceptance criteria to demonstrate substantial equivalence to the predicate device.