August 3, 2023

ATMOS MedizinTechnik GmbH & Co. KG
Reinhold Storch
Manager Projects & Technical Editing ENT/GYNE/FEES
Ludwig-Kegel-Str. 16
Lenzkirch, BW 79853
Germany

Re: K232015
Trade/Device Name: ATMOS Scope (507.7000.0); ATMOS Scope Pro (507.7050.0); ATMOS Scope iPrime (507.7060.0)
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: April 7, 2023
Received: July 6, 2023

Dear Reinhold Storch:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232015

Device Name
ATMOS Scope (507.7000.0); ATMOS Scope Pro (507.7050.0); ATMOS Scope iPrime (507.7060.0)

Indications for Use *(Describe)*
ATMOS Scope is used for endoscopic diagnosis within the nasal lumens and airway anatomy and is intended to provide visualization via a monitor. The ATMOS Scope may only be used by persons with an appropriate medical qualification and who are acquainted with the rhino/laryngoscopic technique.

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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510(k) Summary

Submitter: ATMOS MedizinTechnik GmbH & Co. KG

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Date Prepared: 28.07.2023

Device

Name of Device:	ATMOS Scope (507.7000.0) ATMOS Scope Pro (507.7050.0) ATMOS Scope iPrime (507.7060.0)
Classification Name:	Nasopharyngoscope (Flexible Or Rigid)
Regulation:	21 CFR 874.4760
510(k):	K232015
Device Classification:	Class II
Medical Specialty:	Ear, Nose & Throat
Device Product Code:	EOB

Predicate device

Predicate Manufacturer:	Schoelly Fiberoptic GmbH
Predicate Trade Name:	Schoelly CMOS Video Nasopharyngoscope System
Predicate 510(k):	K143673
Device Product Code:	EOB

Device Description

The ATMOS Scope is a flexible nasopharyngo laryngoscope for endoscopic diagnosis within the nasal lumens and airway anatomy.
The device is an electrical device and consists of a handle for the user and a flexible, steerable part that is inserted into the patient. The deflection lever can be easily operated with the thumb and enables precise control of the endoscope tip at an angle of 2 x 135°. This makes it easy to examine even hard-to-reach regions in the nose, or throat.
The device contains two integrated LED light sources that provide bright and homogeneous illumination in the complete field of view. With the help of a 1280 x 800-pixel image sensor at the distal end of the flexible part and the electronics built into the handle, a digital image is generated.
For taking and saving photos and videos, the ATMOS Scope has two separate function keys located directly on the handle. This can be displayed as the endoscopic image on a connected PC with video software. The endoscopic image is used for visual diagnostics by the user.
The ATMOS Scope is delivered in a non-sterile condition.

Indication for use

ATMOS Scope is used for endoscopic diagnosis within the nasal lumens and airway anatomy and is intended to provide visualization via a monitor. The ATMOS Scope may only be used by persons with an appropriate medical qualification and who are acquainted with the rhino/laryngoscopic technique.

Intended patient target group

Patients for whom an endoscopic examination is generally indicated. The use of the device also depends on the patient's general condition and must therefore be critically evaluated by the responsible physician before each use.

Comparison of technological characteristics with the predicate device
The following characteristics were compared between the subject device and the predicate device to demonstrate substantial equivalence:

Similarities		
Feature	**Subject Device ATMOS Scope**	**Predicate Device K143673**
Indications for Use	ATMOS Scope is used for endoscopic diagnosis within the nasal lumens and airway anatomy and is intended to provide visualization via a monitor. The ATMOS Scope may only be used by persons with an appropriate medical qualification and who are acquainted with the rhino/laryngoscopic technique.	The Schoelly CMOS Video Nasopharyngoscope System may only be used by persons with appropriate medical qualifications and who are acquainted with the rhino/laryngoscopic technique. The endoscope is used for endoscopic diagnosis within the nasal lumens and airway anatomy and is intended to provide visualization via a video monitor.
Design	Flexible and steerable fiberoptic endoscope for diagnostic purposes	Flexible and steerable fiberoptic endoscope for diagnostic purposes
Material	The handle is made of aluminum (hard anodized and coated) with a multifunctional surface coating. The insertion tube is made of PEEK, FKM, TPU, and sapphire glass.	The handle is made of aluminium (hard anodized and coated) with a multifunctional surface coating. The insertion tube is made of PEEK, FKM, TPU, and sapphire glass.
Chip-on-Tip	Chip-on-Tip technology integrated: CMOS image sensor at the tip of the insertion tube	Chip-on-Tip technology integrated: CMOS image sensor at the tip of the insertion tube
Lightning	LED (2 LEDs)	LED (2 LEDs)
Deflection	2 x 135°	2 x 135°
Weight	0,4 kg	0,4 kg
USB Connection	Yes	Yes
Focus Range	6 – 60 mm	6 – 60 mm
Delivery Status (Sterilization)	None-sterile	None-sterile

Table 1 Similarities between a subject device and predicate device

Differences			
Feature	**Subject Device ATMOS Scope**	**Predicate Device K143673**	**Justification**
Image Sensor	1/14.25" CMOS 1280 x 800	1/18" CMOS 328 x 250	CMOS sensors are installed as image sensors for both subject device as well as predicate device. These provide images of different resolutions. In comparison with the predicate device, the effective resolution of the ATMOS Scope is higher (resulting from the combination of its slightly larger field of view and the higher pixel number of its image sensor). The higher resolution provides an optimized view of the anatomy. Therefore, the aspect “safety and effectiveness” is not impacted negatively due the different image resolution with the ATMOS Scope.
Resolution of the image sensor (Pixel)	800 x 800 (640.000)	328 x 250 (82.000)	
Connection to PC	Connection to PC via USB (control and video signal), control of LEDs and buttons.	The device handle shall be connected to the CCU. CCU can be connected to the PC via USB (control functions and video signal), monitor via s-video (video signal), and stroboscope. Internal control of LEDs and button action.	Both, subject device as well as predicate device are using a USB connector. While K143673 requires a control unit to be connected, ATMOS Scopes can be connected directly to the PC. This does not change the risk for the patient.
Field of view	90°	85°	In comparison with the predicate device, the effective resolution of the ATMOS Scope is higher (resulting from the combination of its slightly larger field of view and the higher pixel number of its image sensor). The larger field of view provides an optimized view of the anatomy. Therefore, the aspect “safety and effectiveness” is not impacted negatively due the difference in the field of view with the ATMOS Scope.

Stroboscopy	Not supporting stroboscopy	stroboscopy	This feature removed from subject device due to patient complaints in K143673.
Sterilization (optional)	The ATMOS Scope with attachment for pressure compensation can be sterilized by using a Low-Temperature Hydrogen Peroxide Gas Sterilization Method. This sterilization process can be optionally conducted after one of the reprocessing methods. The following parameter of the sterilization processes are validated: H_2O_2 Concentration [mg/L]: 16 Plasma power [W]: 350W Cycle Duration [min]: 58 Deep Vacuum [mTorr]: 275 The second validated sterilization method is performed in the SYSTEM 1E® Liquid Chemical Sterilant Processing System with standard liquid chemical sterilization (LCS) cycles using S40® Sterilant.	Flexible Schoelly endoscope with air-exhaust can also be gas sterilized using ethylene oxide Specification: Gas mixture 6% Eto, 94% CO_2 Temperature 131°F+/-5°F, 55°C+/-2°C Relative air humidity 40-90% Pressure (overpressure), 17bar (17kpa) Exposure time 120 mins	Validation tests were performed according to FDA recognized standards and Guidance to provide performance data in support of the substantial equivalence determination:
Reprocessing	The manual reprocessing method consists of the manual cleaning process by using the Dual enzymatic cleaning detergent MetriZymeTM (MetriSPONGE; company Metrex) or Cidezyme (ASP®) and the manual high-level disinfection process by using the ready-to-use solution CIDEX® OPA (ASP®) for 18 minutes at a minimum temperature of 20°C.	Place the endoscope and the unscrewed parts in a suitable disinfection solution (which can also double up as a cleaning solution used should be permitted by the manufacturer for such use, Material compatibility release exist for the following disinfectants • Gigasept FF, Schulke & Maye GmbH • Lysetol FF • Helipur HplusN, B Braun Medical AG • Cidex, Johnson&Johnson	Validation tests were performed according to FDA recognized standards and Guidance to provide performance data in support of the substantial equivalence determination

Table 2 Differences between a subject device and predicate device

The technological differences do not raise different questions of safety and effectiveness.

Performance data
The following performance data were provided in support of the substantial equivalence determination.

Human factors testing
The human factors testing is conducted regarding to the dimensions of the applied part (length and diameter and deflection/angle measurement) and the particular requirements for the basic safety and essential performance of endoscopic equipment according to the standard IEC 60601-2-18 were successfully tested.

Optical performance test and photobiological safety of lamp system
An evaluation according to the standard IEC 62471:2006 was conducted and the used LEDs were classified in risk group 2. Additionally, due to the integrated optical fibers, the spectral light range of the LED is limited. Summarized all aspects considered and the measurements prove that the photobiological safety of the ATMOS Scope product is guaranteed and there is no risk as well as no hazard from the light source.

Sterilization validation
Both sterilization processes were validated by EN ISO 14937 (Annex D), AAMI TIR 12, and ANSI/AAMI ST79 and can be optionally conducted after one of the reprocessing methods. First sterilization process is using a Low-Temperature Hydrogen Peroxide Gas Sterilization Method. The second validated sterilization method is performed in the SYSTEM 1E® Liquid Chemical Sterilant Processing System with standard liquid chemical sterilization (LCS) cycles using S40® Sterilant.

Biocompatibility evaluation
Biocompatibility evaluation of subject device ATMOS Scope was performed to comply with the specifications as per standard ISO 10993-1:2018 as well as the FDA Guidance Documents and the effectiveness of the biocompatibility of the ATMOS Scope.

Reprocessing Testing
The reprocessing method consists of a cleaning process conducted and validated by AAMI TIR 30: 2011 and a high-level disinfection process conducted and validated by ASTM E 1837-96 (2014).
The manual cleaning process can be conducted by using the Dual enzymatic cleaning detergent MetriZymeTM (MetriSPONGE; company Metrex) or Cidezyme (ASP®) and the manual high-level disinfection process by using the ready-to-use solution CIDEX® OPA (ASP®).

Electrical safety and electromagnetic compatibility (EMC)
To ensure safe operation of ATMOS Scope, tests were performed according to IEC 60601-1:2005. All clauses of this standard are evaluated and assessed in the corresponding risk assessment file.
To measure the ability of ATMOS Scope to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbance to anything in that environment, Electromagnetic Compatibility Test according to IEC 60601-1-2 Edition 4.0 2014-02 was performed. With a risk-based approach required tests and acceptance criteria were defined.

Software Verification and Validation
Embedded software does not provide support for basic safety or essential performance. Failure of the software does not lead to a risk, therefore PEMS (IEC 60601-1 section 14) does not apply. Every firmware function was validated, and the requirements traceability matrix was documented to prove that requirements have been fulfilled.
Digital image after generation can be displayed on a connected PC with any video software. Due to this requirement the USB connection was checked regarding their configuration, USB device name “ATMOS Scope” and used live image broadcast according to the USB Video Device Class Specification. Summarized all tests regarding to the firmware were passed successfully.

Labelling
All labeling and documentation associated with the ATMOS Scope are in compliance with 5-117 AAMI ANSI ISO 15223-1 3rd edition 2016-11-01, Medical Devices - Symbols To Be Used With Medical Devices Labels, Labeling, And Information To Be Supplied - Part 1: General Requirements. This is not subject to test requirements and no test report is provided.

Conclusion
Non-clinical, simulated use und human factors testing were performed to compare the performance of the subject device and the predicate device using identical inputs. Testing results demonstrated that the

performance of the subject device is equivalent to the predicate device for each software, electrical and mechanical design specification.

A risk analysis was completed, and risk controls were implemented. Human factors testing was conducted to demonstrate that the ergonomics of patient and user interfaces for the subject device are equivalent to the predicate device.

Based upon the intended use, descriptive information, and performance evaluation provided the ATMOS Scope is substantially equivalent to the currently marketed predicate device K143673.