August 27, 2020

Turkuaz Saglik Hizmetleri Medikal Temizlik Kimyasal Urunler
% Ronald J. Amen
Director
ST&T Research, Inc.
18101 Catherine Circle
Villa Park, CA 92861

Re: K190864
Trade/Device Name: Konix Anti-Fog Solution
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCT
Dated: July 6, 2020
Received: July 28, 2020

Dear Ronald J. Amen:

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,

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190864

Device Name

KONIX(R) Anti-Fog Solution

Indications for Use *(Describe)*

KONIX Anti-Fog solution is a sterile, disposable, functional, anti-fog solution. The antifog solution is intended to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens. KONIX Antifog Solution is used to prevent the lenses of the imaging device from fogging due to the difference in body temperature before and during endoscopic and laparoscopic procedures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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ST&T DEPARTMENTS:

PHARMACOLOGY/TOXICOLOGY RESEARCH
INTERNATIONAL REGULATORY CONSULTATION
PRODUCT DEVELOPMENT & CLINICAL RESEARCH
PRE-POST MARKET CONSUMER PRODUCT RESEARCH
FDA~FTC~EPA~CUSTOMS LABELING & CLAIMS COMPLIANCE
☐ INFORMATION & CONSULTING: 800-869-4636

INTERNATIONAL, INC.

510(k) Summary

Date prepared: August 26, 2020

I. SUBMITTER

Official Contact Person: Ronald J Amen
ST&T International Inc.
On Behalf of: **Turkuaz Sağlik Hizmetleri Medikal Temizlik Kimyasal Ürünler San. Ve Tic. A.S**
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Contacts: Nurhan Irmak

II. DEVICE INFORMATION

Name of Device: Konix Anti-Fog Solution
Common or Usual Name: Endoscope Anti-fogging Device
510(k) Number K190864
Regulation Name and Number: Endoscope and accessories (21 CFR 876.1500)
Regulatory Class: II
Classification Panel: Gastroenterology/Urology
Product Code: OCT

III. PREDICATE DEVICE

Trade/Device Name: Dr Fog
Common or Usual Name Endoscope Anti-fogging Device
510(k) Number K932449
Regulation Name and Number: Endoscope and accessories (21 CFR 876.1500)
Product Code: OCT
Submitter: O.R Concepts, INC.
Submitter address: 200 N. Oak St. Roanoke, TX 76262

IV. DEVICE DESCRIPTION

Konix Anti-Fog Solution is a single-use, sterile, and biocompatible laparoscopic accessory device. The product is released to the market as sterile and disposable with one polyurethane foam pad in a 6 ml polyethylene bottle. Secondary packaging is composed of PET film and Medical Kraft Sealing Paper.

Konix Anti-Fog Solution is intended to be used to prevent the lenses of the imaging device from fogging due to the difference in body temperature before and during endoscopic and laparoscopic procedures.

The mechanism of defogging or anti-fogging action of Konix Anti-Fog Solution, works by physically changing the water droplets that form on the lens surface from round droplets, to a flat transparent sheet of water, a phenomenon known as 'wetting'.

V. INDICATIONS FOR USE

KONIX Anti-Fog solution is a sterile, disposable, functional, anti-fog solution. The antifog solution is intended to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens. KONIX Antifog Solution is used to prevent the lenses of the imaging device from fogging due to the difference in body temperature before and during endoscopic and laparoscopic procedures.

VI. COMPARISON OF TECHNICAL CHARACTERISTICS WITH PREDICATE DEVICE

Konix Anti-Fog Solution is designed to prevent the lenses of the imaging device from fogging, that is the same as the predicate device. A comparison of the device features, technological characteristics, intended use, and other information demonstrates that Konix Anti-Fog Solution is substantially equivalent to the predicate device. The substantially equivalent comparison table was summarized in Table 5.1.

Device Name	**Proposed Device**	**Predicate Device**	**Comment**
	Konix Anti-Fog Solution	**Dr. Fog Anti-Fog Solution**	
Indication for Use	KONIX Anti-Fog solution is a sterile, disposable, functional, anti-fog solution. The antifog solution is intended to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens. KONIX Antifog Solution is used to prevent the lenses of the imaging device from fogging due to the difference in body temperature before and during endoscopic and laparoscopic procedures.	Dr. Fog Anti-Fog Solution is designed to clear fog from endoscopic camera lenses in order to maintain a clear operating field.	Same
Reusable/Disposable	Disposable	Disposable	
Target Patient Population	The patient who treated by endoscopic and laparoscopic surgery	The patient who treated by laparoscopic surgery	Same

Where Used	Hospital O.R. room	Hospital O.R. room	Same
Contraindications	There are no known contraindications to the patient.		
Method of Introduction	Wiping distal end of the lens by sponge with solution.	Wiping distal end of the lens by sponge with solution.	Same
Safety	The following biocompatibility tests were conducted. - Cytotoxicity Test - Sensitization Test - Intracutaneous Reactivity Test All of the tests passed the requirements as indicated in the applicable standards.	Not known	All of the biocompatibility tests that are indicated in the FDA recognized standards were performed.
Sterilization Method	Gamma-radiation Sterilization (10^{-6} SAL)	Gamma-radiation Sterilization (10^{-6} SAL)	Same
Energy Source	No energy source	No energy source	Same

Through the substantially equivalent comparison table, the differences do not raise any different issues on the safety or effectiveness of the product.

VII. PERFORMANCE DATA

A series of the studies were performed to evaluate the safety and effectiveness of Konix Anti-Fog Solution. The following test results were provided to confirm the product is safe and effective as indicated.

A. Biocompatibility Testing

The biocompatibility test was evaluated per the FDA recognized consensus standard named "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" issued on June 16, 2016, the biocompatibility tests include the following items since the product is classified as the classification.

Nature of Body Contact		**Contact Duration**
Category	**Contact**	
Surface Device	Mucosal membrane Breached or compromised surface	Limited (≤ 24 h)

No.	**Test Name**	**Applicable Standards**	**Comment**
1	Cytotoxicity Test	ISO 10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity	Pass
2	Sensitization Test	ISO 10993-10:2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization	Pass
3	Intracutaneous	ISO 10993-10:2010 Biological Evaluation Of	Pass

	Reactivity Test	Medical Devices - Part 10: Tests For Irritation And Skin Sensitization	

All of the test studies listed above showed that Konix Anti-Fog Solution did not raise any safety issues and is biocompatible.

B. Sterilization Validation and Shelf Life Study

The product is designed to perform gamma-radiation sterilization prior to place into the market, therefore the following studies should be evaluated by the applicable standards/guidance.

a. Gamma-Radiation Sterilization Validation Study

The gamma-radiation sterilization validation study was performed per the requirements of the FDA recognized consensus standards listed below.

- ISO 11137-2:2013 Sterilization of Health Care Products - Radiation - Part 2: Establishing the Sterilization Dose

- ISO 11737-1:2018 Sterilization of Medical Devices - Microbiological Methods - Part 1:Determination of A Population of Microorganisms on Products

- ISO 11737-2:2019 Sterilization of Medical Devices - Microbiological Methods - Part 2: Tests of Sterility Performed in The Definition, Validation And Maintenance Of A Sterilization Process

The method used for gamma-radiation sterilization validation study was ISO11137-2 Method 1 multiple production batches (7.2), since the product bioburden was less than 1 CFU/sample. The test reports showed that the product can become sterile when the routine sterilization parameter was controlled at the dose of no less than 13,9 kGy, which meets the regulatory requirement of sterile condition (SAL < 10-6).

b. Product Aging Validation Study (Shelf Life Study)

The product aging validation study was performed for 3 years standards "ASTM f1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices" to determine the shelf life of the product, since the product is supplied in the sterile status.

The Aging Validation Study included the following test studies.

Since the shelf life of the product is proposed to be stored for 3 years, the aging validation study is performed which included the following test items.

No.	Test Name	Applicable Standards	Comment
1	Package Integrity Test (Dye penetration Test)	ASTM F1929-15 Standard Test Method For Detecting Seal Leaks In Porous Medical Packaging By Dye Penetration	Pass
2	Seal Peel Strength Test	ASTM F88/F88M-15 Standard Test Method For Seal Strength Of Flexible Barrier Materials	Pass
3	Product Sterility Test	ISO 11737-2:2019 Sterilization Of Medical Devices -Microbiological Methods - Part 2: Tests Of SterilityPerformed In The Definition, Validation And Maintenance Of A Sterilization Process	Pass
4	Product Stability Studies (Fog Resistance Test)	N/A (followed by the internal testing protocol)	Pass

All of the aging test data showed that the product can be safe and effective during its predetermined shelf life. Hence, the sterile assurance level and the functional specification of the product meet the firm's definition and regulatory requirement, the shelf life of the product is 3 years.

C. Product Performance Test:
The test result of the fog resistance test shows that Konix Antifog Solution is effective.

VIII. CONCLUSIONS
Based on the previous data and comparison to the predicate device, Konix Anti Fog Solution is as safe and effective as the predicate device and do not raise any new issues of safety and effectiveness.