November 5, 2020

SafKan, Inc.
Allison Komiyama
Principal Consultant
Acknowledge Regulatory Strategies, LLC
2251 San Diego Avenue
Ste B-257
San Diego, California 92110

Re: K201877
Trade/Device Name: OtoSet - Ear Cleaning System
Regulation Number: 21 CFR 880.6960
Regulation Name: Irrigating syringe
Regulatory Class: Class I
Product Code: KYZ
Dated: October 2, 2020
Received: October 5, 2020

Dear Allison Komiyama:

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,

for Malvina Eydelman, M.D.
Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201877

Device Name
OtoSet – Ear Cleaning System

Indications for Use *(Describe)*
The OtoSet – Ear Cleaning System (OtoSet) is indicated to remove earwax from the external ear canal with irrigation and suction in adults.

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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510(k) Summary
K201877

DATE PREPARED
November 3, 2020

MANUFACTURER AND 510(k) OWNER
SafKan, Inc.
1665 E 18th Street #205, Tucson, AZ 85719, USA
Telephone: +1 (253) 332-9770
Official Contact: Sahil Diwan, Co-Founder & CEO

REPRESENTATIVE/CONSULTANT
Allison C. Komiyama, Ph.D., R.A.C.
Erin A. Gontang, Ph.D.
AcKnowledge Regulatory Strategies, LLC
Telephone: +1 (619) 458-9547
Email: akomiyama@acknowledge-rs.com, egontang@acknowledge-rs.com
Website: www.AcKnowledge-RS.com

DEVICE INFORMATION
Proprietary Name/Trade Name: OtoSet – Ear Cleaning System
Common Name: Irrigating Syringe
Regulation Number: 21 CFR 880.6960
Class: I
Product Code: KYZ

PREDICATE DEVICE IDENTIFICATION
The OtoSet – Ear Cleaning System is substantially equivalent to the following devices:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
Class I Exempt	Welch Allyn Ear Wash System/ Welch Allyn, Inc.	✓
Class I Exempt	Bionix OtoClear/Bionix Development Corp.	Reference Device

The predicate and reference devices have not been subject to a design related recall.

DEVICE DESCRIPTION
The OtoSet – Ear Cleaning System (OtoSet) is an automated ear irrigation device used to remove earwax, or cerumen, from the external ear canal of adults. The OtoSet consists of an adjustable head strap, two ear units, two single-patient-use disposable ear tips, and two single-patient-use disposable waste containers.

In addition to the disposable ear tips and waste containers, each ear unit houses a solution

container, liquid pump, vacuum pump, printed circuit board electronics, rechargeable batteries, and electrical and plumbing elements to connect these items together. The device can be used to clean the left, right, or both external ear canals at the same time.

The OtoSet includes components that come in contact with the patient during use. The single-patient-use disposable ear tips, ear pads and head strap pad (all made of silicone rubber) are surface contacting components having limited contact duration (< 24 hours) with intact skin.

INDICATIONS FOR USE

The OtoSet – Ear Cleaning System (OtoSet) is indicated to remove earwax from the external ear canal with irrigation and suction in adults.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

SafKan believes that the OtoSet is substantially equivalent to the predicate device based on the information summarized here:

The intended use and indications for use of the OtoSet are the same as the primary predicate device, the Welch Allyn Ear Wash System. Both devices are irrigation devices used to remove earwax from the external ear canal, and control irrigation pressure via a pump. The OtoSet and the Welch Allyn Ear Wash System also control suction pressure via vacuum.

The OtoSet and the predicate device use non-sterile single-patient-use disposable ear tips.

The technological characteristics of the OtoSet are very similar to the predicate device, in its function, principle of operation, performance, and biocompatibility. These technological characteristics have undergone testing to ensure the device is as safe and effective as the primary predicate.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the OtoSet. The following tests were performed to demonstrate safety based on current industry standards:

Cleaning validation: Device cleaning was validated using ANSI/AAMI TIR 12 and ISO 10993-5.

Biocompatibility: Patient contacting material met the requirements outlined in ISO 10993-1.

Software Verification: The software development and testing were executed in compliance to IEC 62304.

Electromagnetic Compatibility and Electrical Safety: The subject device was tested in compliance to ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, IEC 60601-1-2, FCC 47 CFR 15 Subpart B and ANSI C63.4, and IEC 62133-2.

Usability testing: The usability of the subject device was assessed by 15 individuals who adequately represented the intended user population. All participants successfully performed simulated scenarios and sub-tasks, and provided feedback on the use of the subject device.

SUMMARY OF CLINICAL TESTING

Clinical testing of the OtoSet included two studies. The first study (n=31 subjects, 62 ears) evaluated the OtoSet against the device's primary predicate, the Class I Welch Allyn Ear Wash System. The objective of the study was to evaluate the effectiveness of earwax removal (using a 0-3 Degree of Occlusion Scale) of the OtoSet compared to the Welch Allyn Ear Wash System. The second study (n=23 subjects, 31 ears) evaluated the subject device's ability to effectively remove earwax (also using a 0-3 Degree of Occlusion Scale).

The data in these studies show that the OtoSet is equivalent to the predicate device in terms of removing earwax from the external ear canal. The results also support the proposed intended use of the OtoSet.

CONCLUSION

Based on the testing performed, non-clinical (biocompatibility, software validation, electromagnetic compatibility and electrical safety, and usability testing), and clinical testing, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device. The similar indications for use, technological characteristics, and performance characteristics for the proposed OtoSet – Ear Cleaning System are assessed to be substantially equivalent to the predicate device.