June 14, 2022

Zsquare, Ltd
Liat Diamant-Porat
CEO, LDP Consulting Ltd.
43 Hasivim Street
Petah Tikva, 4959501
Israel

Re: K220004
Trade/Device Name: Zsquare ENT-Flex
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: May 4, 2022
Received: May 10, 2022

Dear Liat Diamant-Porat:

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 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)*
K220004

Device Name
Zsquare ENT-Flex

Indications for Use *(Describe)*
Zsquare ENT-Flex endoscope is intended to visualize the internal cavities of the ear, airways, nose and sinus cavities during diagnostic endoscope 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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510(k) SUMMARY

Owner's Name & Address	Zsquare, Ltd 43 Hasivim Street Petah Tikva, Israel 4959501 Phone: +972-3-698-7600
Contact Person	Liat Diamant Porat, LL.B, B.Sc LDP Consulting Ltd. 44 Hey Beiyar Street Tel-Aviv, Israel liat@ldp-consulting.com +972-50-525-2099
Date	June 09, 2022
Trade Name	Zsquare ENT-Flex
Common / Classification Name	Ear & Nose Surgery
Product Code	EOB
Classification	Class II
Predicate Device	3NT endoscopy system (K162916), Ambu aScope 4 RhinoLaryngo Slim (K191080)
Device Description	Zsquare ENT-Flex endoscope is a flexible, high-resolution endoscope with a narrow insertion diameter composed of a Single-Use Shell, provided sterile, that fully encompasses a reusable Imaging Core. The Zsquare ENT-Flex endoscope is intended to visualize the internal cavities of the ear, airways, nose, and sinus cavities during diagnostic endoscope procedures. The endoscope is to be used with a Console provided by Zsquare in a hospital or clinic environment. This device is designed to reduce the need for high-level disinfection and/or sterilization between patients by providing a sterile disposable Single-Use Shell that is used in combination with a reusable Imaging Core. The Zsquare ENT-Flex system consists of a/an: • Endoscope comprised of a: ○ Disposable Single-Use Shell that is comprised of the handle, the steering mechanism, and the steerable shaft (imaging fiber, illumination fiber and distal optics). It is the only part that contacts the patient and physician's soiled hands and is disposed of at the end of the procedure. ○ Reusable Imaging Core, which is a hand-held multi-use unit containing the optical system that is composed of a lens array and a camera. At the end

of a procedure, the Imaging Core is disengaged from the Shell and cleaned with ethanol wipes.

- Console – comprised of a/an:
  - Illumination Unit
  - Camera Control Unit (CCU)
  - Monitor/Screen
  - Keyboard with touchpad
  - Footswitch
  - Cart

The console enables the image-processing. A data cable connects to the endoscope and transfers the video data to the image-processing unit. The image is transferred and displayed on a graphical user interface (i.e.: monitor).
Power is supplied to the camera contained in the Imaging Core by a cable from the CCU. A second cable is connected to the illumination source to control the illumination.

Indications for use

Zsquare ENT-Flex endoscope is intended to visualize the internal cavities of the ear, airways, nose, and sinus cavities during diagnostic endoscope procedures.

Technological Characteristics

Optics Performance:	
Field of View	93° (air)
Direction of View	Forward view
Depth of Field	3.5 – 50 mm
Optimal working distance	7 mm
Insertion Tube Diameter	2.3mm
Insertion Tube Working Length	290 mm
Articulation	130°
Reusability	Single-use disposable unit, reusable imaging unit

Non-Clinical Performance Data

PERFORMANCE – BENCH TESTING
Bench testing included Image Parameter Testing (Including ISO 8600), Shaft Dimensional Visual Inspection and Mechanical Properties, Zsquare ENT-Flex Illumination Source (ZEIS) HW & Optical Performance Testing, Reusable to Console Mating Cycles Testing, Reusable to Disposable Mating Cycles Testing, IP Testing of the Imaging Core, Color Performance Test, Glass to Glass Latency Testing.

STERILIZATION, PACKAGING & SHELF-LIFE
Sterilization validation of the Single-Use Shell was tested according to Sterilization ISO 11135.

The shelf life of the Zsquare ENT-Flex Shell (use before date) is established through an accelerated aging study according to ISO 11607.

Testing of the product packaging after transportation/environmental and shelf-life simulation showed that the sterile barrier packaging integrity is maintained, thus assuring maintenance of the product sterility assurance level (SAL) of 10^{-6}.

The Imaging Core requires Intermediate Level Disinfection, and this process kills pathogenic and other microorganisms by physical or chemical means.

The reprocessing validation was conducted, according to ST-724-2021/P Manual Cleaning Intermediate Level Disinfection Validation.

BIOCOMPATIBILITY
Biocompatibility assessments were performed in accordance with the appropriate risk category requirements, as defined in ISO 10933-1.

SOFTWARE
Software verification and validation testing was performed to demonstrate that the software in the subject device meets design specifications.

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY
General requirements for basic safety and essential performance IEC 60601-1. Electrical safety for endoscopes in IEC 60601-2-2018. Electromagnetic compatibility testing per IEC 60601-1-2. Photobiological safety per IEC 62471.

Substantial Equivalence

The Zsquare ENT-Flex endoscope has similar indications for use and technological features to the predicate devices, the 3NT Endoscopy System and Ambu aScope 4 RhinoLaryngo Slim. These devices are single-use endoscopes, designed to visualize the internal cavities of the ear, airways, nose, and sinus cavities. The endoscopes are supplied sterile and should not be reused. The 3NT Endoscopy System contains an integrated working channel that allows irrigation through a single channel, whereas the Zsquare ENT-Flex endoscope and the Ambu endoscope do not contain a working channel, however, this difference does not introduce hazards and does not raise questions of safety or effectiveness. The Zsquare ENT-Flex endoscope device has the same basic

device design as the 3NT Endoscopy System and Ambu aScope 4 RhinoLaryngo Slim predicate devices. The principle of operation is similar between the devices, as is the expected workflow, and most of the device features.

All devices include a single-use unit connected to a reusable unit, and a CCU. All endoscopes provide a single-use, sterile distal unit, which is disposed of at the end of the procedure. All single-use distal units are ETO sterilized. All single-use disposable distal units include the insertion tube that is in direct contact with the patient. The 3NT endoscope is composed of a multi-use handle (includes controls for angulation of the endoscope tip) that engages the single-use insertion tube. The Zsquare ENT-Flex disposable unit completely encompasses the Imaging Core and includes a handle so that the physicians' sterile hands come in contact only with the disposable unit (images are captured with a foot switch) to minimize cross-contamination. The Ambu endoscope is entirely disposable, however is for use with the Ambu aView 2 Advance that requires disinfection by wipes (that are based on Isopropyl alcohol 70-80 %, Isopropyl alcohol/Ammonium Chloride or Isopropyl alcohol/Ethanol.) The Ambu endoscope contains optics and illumination. At the end of the procedure the single-use endoscope unit (or the whole endoscope for Ambu) in all devices is disengaged and disposed of; the Imaging Core of Zsquare is cleaned with a lint-free cloth dampened with 70% isopropyl alcohol, which is considered intermediate level sterilization, as it is not exposed to contamination. It is similar to the reprocessing recommendations for the reusable Ambu monitor. The 3NT multi use unit is reprocessed and autoclaved between patients since the physician holds the handle during the procedure.

The Zsquare illumination system includes an external illumination source and illumination fiber in the shaft similar to the 3NT; the only difference is that the Zsquare illumination source is separate from the CCU and the 3NT illumination source is embedded in the CCU. The Ambu illumination system is two LED lights embedded in the tip. The Zsquare endoscope contains an optical system within the Imaging Core that is composed of a lens array and a camera that is connected to a console (control unit), which includes an image/video processor and a white LED light source. Similarly, the 3NT endoscope is composed of a multi-use handle that engages the single-use insertion tube and a Camera control unit (CCU) which includes a video processor and a white LED light source. The 3NT CCU includes an attachment cable which connects to the single-use endoscope, receives video images from the endoscope, and delivers LED light to the endoscope. The Ambu aScope 4 RhinoLaryngo Slim is to be used with the separately sold Ambu® aView™ 2 Advance, the

equivalent of the CCU unit. In all devices the video data is processed in a separate image-processing unit.
The minor differences in technological characteristics do not raise new types of safety or effectiveness questions. Performance testing and validations confirm that these differences do not adversely impact performance. Therefore, the proposed device is substantially equivalent to the predicate devices.

Conclusions

Based on the comparison of intended use, indications for use, technological characteristics and performance testing, Zsquare Ltd. believes that the Zsquare ENT-Flex is substantially equivalent to its predicates.