February 16, 2024

Biowy Corporation
Zhihua Lu
President
27031 Vista Terrace
Lake Forest, California 92630

Re: K233658
Trade/Device Name: Biowy Tym Tube (TT)
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy Tube
Regulatory Class: Class II
Product Code: ETD
Dated: January 15, 2024
Received: January 16, 2024

Dear Zhihua Lu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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)*
K233658

Device Name
Biowy Tym Tube (TT)

Indications for Use *(Describe)*

The Biowy Tym Tube products are indicated for where chronic Eustachian tube dysfunction does not respond to conventional therapy.

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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Biowy Corporation

Biowy Tym Tube 510(k)

Traditional 510(k)

510(k) Summary

PROPRIETARY NAME:	Biowy Tym Tube		
COMMON NAME:	Tympanostomy Tube		
REGULATION NAME:	Tympanostomy Tube		
DEVICE CLASS:	II		
REGULATION NUMBER:	21 CFR 874.3880		
PRODUCT CODE:	ETD		
CLASSIFICATION NUMBER:	21 CFR 874.3880		
PREDICATE DEVICE:	Otological Ventilation Tubes (K830228)		
SPONSOR:	**Biowy Corporation** 27031/27002 Vista Terrace Lake Forest, CA 92630 – USA		
CONTACT PERSON:	Arthur Lu Telephone No. 1-(949) 305-8211 Fax Number: 1-(866) 506-5094		
STATEMENT OF INTENDED USE:	Indicated where chronic Eustachian tube dysfunction does not respond to conventional therapy.		
DEVICE DESCRIPTION:	The tympanostomy tube is a silicone tube that is intended to provide ventilation and drainage to the middle ear.		
SAFETY AND EFFECTIVENESS INFORMATION:	Biocompatibility testing, according to ISO 10993, has been performed and the devices have been shown to be safe, non-toxic, and biocompatible.		
SUMMARY OF TECHNOLOGICAL SIMILARITIES and DIFFERENCE (BETWEEN THE BIOWY TYM TUBE AND THE PREDICATE)		**Subject Device**	**Predicate**
	Name	Biowy Tym Tube (K233658)	Otological Ventilation Tubes (K830228)
	Use	Silicone vent tube to be placed across the tympanic membrane to allow for middle ear ventilation and fluid drainage.	Silicone vent tube to be placed across the tympanic membrane to allow for middle ear ventilation and fluid drainage.
	Materials	Silicone	Silicone
	Shape	Tube	Tube
	ID	1.14mm	1mm
	OD	1.6mm	1.4mm
	Length	2.20mm	various
	Sterility	Sterile (by EO)	Sterile (by EO)
PERFORMANCE:	The Biowy Tym Tube devices were tested successfully to fully characterize performance.		

<table>
<tr><td></td><td>Below is a tabulated list of all the performance testing that was provided in support of the substantial equivalence of the subject device:

1. Sterility: This submission is supported by appropriate sterilization and shelf-life validation.
2. Pyrogenicity: The device is labeled non-pyrogenic. Three production lots of the test article identified as Biowy Tym Tube, were validated for LAL Endotoxin testing using the Kinetic-Chromogenic test method.
3. Bench Testing results are summarized on the table below:

<table>
<tr><th>Biowy Tym Tube</th><th>Standards/Requirements</th><th>Results</th></tr>
<tr><td>Visual Inspection</td><td>No visual defects</td><td>Met requirements</td></tr>
<tr><td>Compression</td><td>Comparable to predicate</td><td>Met requirements</td></tr>
<tr><td>Tensile</td><td>Higher than that needed for placement and removal</td><td>Met requirements</td></tr>
</table>
</td></tr>
<tr><td>COMPARISON TO THE PREDICATE DEVICE:</td><td>These device family, with respect to material composition, device characteristics and intended use, are substantially equivalent to the predicate device (Otological Ventilation Tubes, cleared under K830228).</td></tr>
</table>

CONCLUSION:

The Biowy Tym Tube meets all the predetermined performance acceptance criteria of the testing performed and the performance data were determined to be comparable to the properties of the predicate device. Therefore, the Biowy Tymp Tube is substantially equivalent to the Otological Ventilation Tubes (K830228), concurrence date February 28, 1983.

The predicate device has not been removed from the market at the initiative of the Commissioner of Food and Drugs or has not been determined to be misbranded or adulterated by a judicial order.