February 21, 2019

Taiwan Biomaterial Co., Ltd.
Monoj Kalita
Deputy Manager, Regulatory Affairs
6F, No. 26-1, Sec.2, Shengyi Rd.
Zhubei, 30261 Taiwan

Re: K190105
Trade/Device Name: ZOOM Aspiration Pump
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: JCX
Dated: January 18, 2019
Received: January 22, 2019

Dear Monoj Kalita:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

Digitally signed by David Krause -S
Date: 2019.02.21 14:10:37 -05'00'

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)* *K19O1O5*

Device Name
ZOOM Aspiration Pump

Indications for Use *(Describe)*

ZOOM Aspiration Pump
The ZOOM Aspiration Pump is intended for general suction use in hospitals or clinics.

ZOOM Canister
The ZOOM Canister is intended to collect aspirated fluids for disposal and prevent fluid ingress from damaging the ZOOM Aspiration Pump.

ZOOM Aspiration Tubing
The ZOOM Aspiration Tubing Set is intended to connect a suction catheter to the ZOOM Canister of the ZOOM Aspiration Pump and to allow the user to control the fluid flow.

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.

ZOOM™ Aspiration Pump

Special 510(k)

510(K) SUMMARY

1.1. APPLICANT INFORMATION

Applicant Name	----	Taiwan Biomaterial Co., Ltd. (TWBM)
Address	----	6F, No. 26-1, Sec.2, Shengyi Rd., Zhubei City, Hsinchu County 30261, Taiwan.
Telephone	----	+886-3-6683088
Fax	----	+886-3-6683099
Contact Person	----	Monoj Mon Kalita, Ph.D. Deputy Manager, Regulatory Affairs Phone: +886-3-6683088 ext. 309 Email: mon@twbm.com.tw
Date Prepared	----	February 5, 2019

1.2. SUBJECT DEVICE

Trade Name	----	ZOOM™ Aspiration Pump
Common/Usual Name	----	Powered Suction Pump
Device Class	----	Class II
Regulation Number	----	21 CFR 878.4780
Classification Name	----	Apparatus, Suction, Ward Use, Portable, AC-Powered
Product Code	----	JCX

1.3. PREDICATE DEVICE NAME

TWBM Pump (K180115)

1.4. INTENDED USE

ZOOM Aspiration Pump
The ZOOM Aspiration Pump is intended for general suction use in hospitals or clinics.
ZOOM Canister
The ZOOM Canister is intended to collect aspirated fluids for disposal and prevent fluid ingress from damaging the ZOOM Aspiration Pump.
ZOOM Aspiration Tubing
The ZOOM Aspiration Tubing Set is intended to connect a suction catheter to the ZOOM Canister of the ZOOM Aspiration Pump and to allow the user to control the fluid flow.

1.5. DEVICE DESCRIPTION

The ZOOM™ Aspiration Pump (ZOOM Pump) is an AC powered oil-less positive displacement pump capable of consistently delivering vacuum (0-29 inHg) for the removal of bodily fluids. The ZOOM Pump housing is fitted with a power (ON/OFF) button, one vacuum regulator, an analog pressure gauge and sliding canister shelf. The ZOOM Pump is provided non-sterile.

There are two accessories for the ZOOM Pump, the ZOOM™ Canister and ZOOM™ Aspiration Tubing. The ZOOM™ Canister is a non-sterile, single use 1000 mL canister which collects the removed bodily fluids. The ZOOM Canister is positioned in the sliding canister shelf and connected to the ZOOM Pump via the canister tubing and connectors. The ZOOM Aspiration Tubing is sterile, single use and connects to the blue connector on the canister lid.

1.6. TECHNOLOGICAL AND REGULATORY ATTRIBUTES COMPARISON

The technological and regulatory attributes of the subject device are compared with the predicate device as illustrated in the table below:

Attributes	TWBM Pump (Predicate Device)	ZOOM™ Aspiration Pump (Subject Device)
510(k) Number	**K180115**	**K190105**
Classification Name	Apparatus, Suction, Ward Use, Portable, AC-Powered	Same as predicate
Class	II	Same as predicate
Product Code	JCX	Same as predicate
Intended Use	General suction use in hospitals or clinics	Same as predicate
Product Type	AC-Powered suction pump	Same as predicate
Manufacturer	TWBM	Same as predicate
Electrical requirement	110-120Vac 60Hz	Same as predicate
Flow Rate	0-0.8 SCFM (0-23 LPM)	Same as predicate
Vacuum Range	0-29 inHg (0-737mmHg)	Same as predicate
Noise level	<60dB	Same as predicate

Attributes		TWBM Pump (Predicate Device)	ZOOM™ Aspiration Pump (Subject Device)
Dimensions		12.2in×6.2in×11.3in (30.9cm×15.7cm×28.7cm)	12.3in×7.2in×12.4in (31.3cm×18.3cm×31.5cm)
Weight		14.8 lb (6.7 kg)	15.2 lb (6.9 kg)
Duty Cycle		45 min (20%) ON/ 3 hours (80%) OFF	45 min (97.8%) ON/ 1 min (2.2%) OFF
Accessories	Canister	TWBM Canister • 1000 mL, • Canister tubing, • Overflow protection valve, • Filter (Microbial, Hydrophobic), • Single Use Only, • Non-Sterile	ZOOM™ Canister • 1000 mL, • Canister tubing, • Overflow protection valve, • Filter (Microbial, Hydrophobic), • Single Use Only, • Non-Sterile
	Aspiration Tubing	N/A	ZOOM™ Aspiration Tubing • Class II Exempt • EO Sterilized • Non-pyrogenic • Biocompatible • Single Use Only • **ID:** 0.110″ • Length: 264.2cm • Flow clamp
Operating Environment		Temp: 65°F~75°F (18°C~ 24°C) Humidity: <75% RH Pressure: Sea Level – 6000 ft (1829m)	Same as predicate
Storage Environment		Temp: -20°F~120°F (-29°C~ 49°C) Humidity: <95% RH	Same as predicate

1.7. SUMMARY OF DEVICE TESTING

ZOOM™ Aspiration Pump was subjected to Electromagnetic Compatibility testing in accordance with IEC 60601-1-2 and performance bench testing in accordance with ISO 10079-1, IEC 60601-1 as well as IEC 60529. Testing for ZOOM™ Aspiration Pump were conducted by following the FDA's "Guidance Document for Powered Suction Pump 510(k)s" (Sept. 30, 1998). All the test results from the performance testing passed the acceptance criteria set forth by the respective standards.

1.8. SUMMARY OF NON-CLINICAL TESTING

The table below highlights the non-clinical performance testing of the ZOOM™ Aspiration Pump and its accessories, conducted for the determination of substantial equivalence with the predicate TWBM Pump and its accessory.

Attributes	Acceptance Criteria	Result (YES/NO)
ZOOM™ ASPIRATION PUMP		
Compliance with ANSI/AAMI ES60601-1 and CAN/CSA C22.2 NO. 60601-1	100% Pass	YES
Compliance with IEC 60601-1-2	100% Pass	YES
Compliance with ISO 10079-1	100% Pass	YES
Compliance with IEC 60529 for IP Code	The requirement for the IP 21 marking should be met.	YES
ZOOM™ CANISTER (COMPLIANCE WITH ISO 10079-1)		
Design and Operational Requirements for ZOOM™ Canister and its Components	100% Pass	YES
ZOOM™ ASPIRATION TUBING		
Operational Requirements for ZOOM™ Aspiration Tubing and its Components (Compliance with ISO 10079-1)	100% Pass	YES
Compliance ISO 10993-1	Biocompatible	YES

1.9. CONCLUSION

Both the ZOOM™ Aspiration Pump as well as the predicate TWBM Pump are AC-Powered Suction Pumps with similar accessories for fluid containment. Additionally, the non-clinical bench testing results and the comparison of technological characteristics, intended use, the principle of operation and operating environment support the determination of ZOOM™ Aspiration Pump to be substantially equivalent to the predicate TWBM Pump. It can be concluded that the subject device performs as safe and effective as the predicate device.