July 24, 2018

Taiwan Biomaterial Co., Ltd.
Monoj Kalita
Regulatory Affairs Specialist
6F, No. 26-1, Sec.2, Shengyi Rd.
Zhubei City, Hsinchu County, Taiwan 30261

Re: K180115
Trade/Device Name: TWBM Pump
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: JCX
Dated: January 12, 2018
Received: January 16, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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

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)*
K180115

Device Name
TWBM Pump

Indications for Use *(Describe)*
TWBM Pump is intended for general suction use in hospitals or clinics.

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.

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SECTION 2: 510(K) SUMMARY

2.1. 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, PhD Regulatory Affairs Specialist Phone: +886-3-6683088 ext. 309 Email: mon@twbm.com.tw
Date Prepared	June 21, 2018

2.2. SUBJECT DEVICE

Trade Name	TWBM 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

2.3. PREDICATE DEVICE NAME

Penumbra Pump MAX™ (K122756)

2.4. INTENDED USE

TWBM Pump is intended for general suction use in hospitals or clinics.

2.5. DEVICE DESCRIPTION

The TWBM Pump is intended for general suction use in hospitals or clinics where secretions, blood and other body fluids must be removed through the application of continuous negative pressure. The TWBM Canister is an accessory to the TWBM Pump and the removed body fluids are collected in it. The TWBM Pump is an AC powered oil-less positive displacement pump capable of delivering up to 29 inHg (737 mmHg) of vacuum to draw fluid and small particles. The TWBM Pump has a plastic casing fitted with a power (ON/OFF) button, one vacuum regulator, an analog pressure gauge and one sliding canister holder. The TWBM Canister is a pre-assembled 1000 mL canister including canister tubing fitted with a microbial filter at the distal end. The canister is fitted with a removable lid for fluid containment and an overflow protection device. The TWBM Canister should be placed in the in-built sliding canister holder, and connect

the TWBM Canister with the TWBM Pump via the connectors of the canister tubing prior to use. Both, the TWBM Pump and the TWBM Canister, are provided non-sterile and are packaged separately.

2.6. 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	Penumbra Pump MAX™ (Predicate Device)	TWBM Pump (Subject Device)
510(k) Number	**K122756**	**K180115**
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	Penumbra Inc.	TWBM
Electrical requirement	100-115Vac 50Hz, 60Hz	110-120Vac 60Hz
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
Dimensions	15.5in×11.2in×13.2in (39.37cm×28.45cm×33.53 cm)	12.2in×6.2in×11.3in (30.9cm×15.7cm×28.7cm)
Weight	22.3 lb (10.1 kg)	14.8 lb (6.7 kg)
Accessories	1 L canister with canister tubing	Same as predicate
Overflow protection	Yes	Same as predicate
Filter	Microbial, hydrophobic	Same as predicate
Operating Environment	Temp: 65°F~75°F (18℃~ 24℃) Humidity: <75% RH Pressure: Sea Level – 6000 ft (1829m)	Same as predicate
Storage Environment	Temp: -20°F~120°F (-29℃~ 49℃) Humidity: <95% RH	Same as predicate

2.7. SUMMARY OF DEVICE TESTING

TWBM Pump was subjected to Electromagnetic Compatibility testing in accordance with IEC 60601-1-2 and performance bench testing in accordance with ISO 10079-1, ANSI/AAMI ES60601-1 and CAN/CSA C22.2 NO. 60601-1 as well as IEC 60529. Testing for TWBM 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.

2.8. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

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

Attributes	Acceptance Criteria	Result (YES/NO)
TWBM 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
TWBM Canister (Compliance with ISO 10079-1)		
Design and Operational Requirements for TWBM Canister and its Components	100% Pass	YES

2.9. CONCLUSION

Both the TWBM Pump as well as the predicate Penumbra Pump MAX™ 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 TWBM Pump to be substantially equivalent to the predicate Penumbra Pump MAX™. It can be concluded that the subject device performs as safe and effective as the predicate device.