

K180115 TWBM PumpJul 24, 2018
189 days to decisionK180115 · Product code: **JCX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k180115/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Suction, Ward Use, Portable, Ac-powered (JCX)
Date received	Jan 16, 2018
Decision date	Jul 24, 2018
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Taiwan Biomaterial Co., Ltd.
Location	Zhubei, TW
Contact	Monoj Mon Kalita
510(k) history	2 submissions · 2 cleared · 2018-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180115/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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