

**K190105 ZOOM Aspiration Pump**Feb 21, 2019  
30 days to decisionK190105 · Product code: **JCX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k190105/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Apparatus, Suction, Ward Use, Portable, Ac-powered (JCX)
Date received	Jan 22, 2019
Decision date	Feb 21, 2019
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190105/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026