

**K181409 Pressure Therapy System PT1003**Feb 19, 2019  
265 days to decisionK181409 · Product code: **IRP** · Physical Medicine  
Source: <https://www.510kdatabase.net/k181409/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	May 30, 2018
Decision date	Feb 19, 2019
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Xiamen Senyang Co., Ltd.</b>
Location	Xinglin Xiamen, CN
Contact	Nina Cai
510(k) history	3 submissions · 3 cleared · 2017-2020

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Shanghai SUNGO Management Consulting Co., Ltd.</b>
Contact	Raymond Luo

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181409/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026