

K210913 V12 PROAug 4, 2021
128 days to decisionK210913 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k210913/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Mar 29, 2021
Decision date	Aug 4, 2021
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Silk Medical GmbH
Location	Dortmund, DE
Contact	Matthew Reid
510(k) history	2 submissions · 2 cleared · 2020-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210913/> 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 May 26, 2026