

K203178 Flexitouch Plus SystemDec 20, 2020
55 days to decisionK203178 · Product code: **JOW** · CardiovascularSource: <https://www.510kdatabase.net/k203178/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Oct 26, 2020
Decision date	Dec 20, 2020
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tactile Systems Technology, Inc. (Db a Tactile Medical)
Location	Minneapolis, MN, US
Contact	Brett Demchuk
510(k) history	3 submissions · 3 cleared · 2016-2020

REGULATORY CONSULTANT

Consulting firm	The Tamarack Group – Mpls, LLC
Contact	Lauren Barnes

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203178/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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