FDA 510(k) Premarket Notification

K201539 Keeogo Dermoskeleton System

CLEARED

Sep 9, 2020
92 days to decision

K201539 · Product code: **PHL** · Neurology
Source: https://www.510kdatabase.net/k201539/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Exoskeleton (PHL)
Date received	Jun 9, 2020
Decision date	Sep 9, 2020
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**B-Temia, Inc.**
Location	St-Augustin-De-Desmaures, CA
Contact	Alexandre Jokic
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Covington & Burling, Llp**
Contact	Kristin Davenport

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