FDA 510(k) Premarket Notification

K183485 CryoVizion System

CLEARED

Aug 28, 2019
254 days to decision

K183485 · Product code: **LDK** · Physical Medicine
Source: https://www.510kdatabase.net/k183485/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Sensing, Optical Contour (LDK)
Date received	Dec 17, 2018
Decision date	Aug 28, 2019
Days to decision	254 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cryos Technologies, Inc.**
Location	Joliette, CA
Contact	John A. Stimpson
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Lok North America, Inc.**
Contact	Louis-Paul Martin

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