FDA 510(k) Premarket Notification

K013019 DATACAPTOR

CLEARED

Dec 18, 2001
102 days to decision

K013019 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k013019/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Sep 7, 2001
Decision date	Dec 18, 2001
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Capsule Technologie**
Location	Deer Field, IL, US
Contact	DANIEL KAMM
510(k) history	5 submissions · 5 cleared · 2001-2019