FDA 510(k) Premarket Notification

K023238 MCPULSE

CLEARED

Feb 19, 2003
145 days to decision

K023238 · Product code: **JOM** · Cardiovascular
Source: https://www.510kdatabase.net/k023238/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plethysmograph, Photoelectric, Pneumatic Or Hydraulic (JOM)
Date received	Sep 27, 2002
Decision date	Feb 19, 2003
Days to decision	145 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Meridian Co., Ltd.**
Location	Songpa-Gu, Seoul, KR
Contact	DANIEL KAMM
510(k) history	7 submissions · 7 cleared · 2000-2011