FDA 510(k) Premarket Notification

K070985 AESCULON CHF, HYPERTENSION & PACEMAKER CLINIC

CLEARED

Feb 1, 2008
301 days to decision

K070985 · Product code: **DSB** · Cardiovascular
Source: https://www.510kdatabase.net/k070985/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plethysmograph, Impedance (DSB)
Date received	Apr 6, 2007
Decision date	Feb 1, 2008
Days to decision	301 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Osypka Medical, Inc.**
Location	La Jolla, CA, US
Contact	MARKUS OSYPKA
510(k) history	7 submissions · 6 cleared · 2002-2013