

**K081035 AESCULON C2, AESCULON CHF CLINIC C2,
AESCULON HYPERTENSION CLINIC C2 AND AESCULON
PACEMAKER CLINIC C2**May 30, 2008
49 days to decisionK081035 · Product code: **DSB** · Cardiovascular
Source: <https://www.510kdatabase.net/k081035/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plethysmograph, Impedance (DSB)
Date received	Apr 11, 2008
Decision date	May 30, 2008
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081035/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 9, 2026