FDA 510(k) Premarket Notification

K083115 MODIFICATION TO INTEL HEALTH GUIDE, MODEL PHS6000

CLEARED

Nov 26, 2008
36 days to decision

K083115 · Product code: **DRG** · Cardiovascular
Source: https://www.510kdatabase.net/k083115/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Oct 21, 2008
Decision date	Nov 26, 2008
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Intel Corp.**
Location	Folsom, CA, US
Contact	TAE-WOONG KOO
510(k) history	3 submissions · 3 cleared · 2008-2010