FDA 510(k) Premarket Notification

K081140 VISENSIA

CLEARED

Jul 17, 2008
86 days to decision

K081140 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k081140/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Apr 22, 2008
Decision date	Jul 17, 2008
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Obs Medical**
Location	Carmel, IN, US
Contact	WAYNE NETHERCUTT
510(k) history	3 submissions · 3 cleared · 2007-2011