FDA 510(k) Premarket Notification

K093881 TRUSIGNAL SPO2 FINGER SENSOR, TRUSIGNAL SPO2 EAR SENSOR, TRUSIGNAL SPO2 WRAP SENSOR

CLEARED

Mar 12, 2010
84 days to decision

K093881 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k093881/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oximeter (DQA)
Date received	Dec 18, 2009
Decision date	Mar 12, 2010
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**GE Healthcare Finland Oy**
Location	Madison, WI, US
Contact	TOMMI JOKINIEMI
510(k) history	30 submissions · 30 cleared · 2007-2023