FDA 510(k) Premarket Notification

K082480 CONTEC POCKET FETAL DOPPLER

CLEARED

Feb 25, 2009
181 days to decision

K082480 · Product code: **KNG** · Radiology
Source: https://www.510kdatabase.net/k082480/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Ultrasonic, Fetal (KNG)
Date received	Aug 28, 2008
Decision date	Feb 25, 2009
Days to decision	181 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Contec Medical System Co., Ltd.**
Location	Zhong Shan, Shanghai, CN
Contact	Diana Hong
510(k) history	12 submissions · 12 cleared · 2008-2019