K100797 FETAL MATERNAL MONITOR MODEL F9 EXPRESS AND EXPRESS

CLEARED

Nov 10, 2010
233 days to decision

K100797 · Product code: **HGM** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k100797/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Mar 22, 2010
Decision date	Nov 10, 2010
Days to decision	233 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Edan Instruments, Inc.**
Location	Shenzhen, CN
Contact	JIGAR SHAH
Website	https://www.edan.com.cn
510(k) history	92 submissions · 92 cleared · 2004-2026