FDA 510(k) Premarket Notification

K052190 FETAL MONITOR, MODELS BT-300 AND BT-200

CLEARED

Oct 4, 2005
54 days to decision

K052190 · Product code: **HGM** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k052190/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Aug 11, 2005
Decision date	Oct 4, 2005
Days to decision	54 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Bistos Co., Ltd.**
Location	Flintville, TN, US
Contact	CHARLIE MACK
510(k) history	11 submissions · 11 cleared · 2005-2025