FDA 510(k) Premarket Notification

K010889 BABY DOPPLEX 3000 MK 2 (BD3000)

CLEARED

Apr 25, 2001
30 days to decision

K010889 · Product code: **HGM** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k010889/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Mar 26, 2001
Decision date	Apr 25, 2001
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Huntleigh Healthcare, Inc.**
Location	Eatontown, NJ, US
Contact	B.J. COLLEYPRIEST
510(k) history	14 submissions · 14 cleared · 1993-2004