FDA 510(k) Premarket Notification

K013281 VERSALAB APM

CLEARED

Apr 18, 2002
198 days to decision

K013281 · Product code: **HGM** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k013281/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Oct 2, 2001
Decision date	Apr 18, 2002
Days to decision	198 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Nicolet Biomedical**
Location	Golden, CO, US
Contact	DAVID W WAGNER
510(k) history	8 submissions · 8 cleared · 1998-2003