FDA 510(k) Premarket Notification

K831361 BETA-PREG

CLEARED

Jun 2, 1983
37 days to decision

K831361 · Product code: **JHJ** · Microbiology
Source: https://www.510kdatabase.net/k831361/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agglutination Method, Human Chorionic Gonadotropin (JHJ)
Date received	Apr 26, 1983
Decision date	Jun 2, 1983
Days to decision	37 days
Third-party review	No

APPLICANT

Company	**Catheter Technology Corp.**
Location	Walker, MI, US
510(k) history	13 submissions · 13 cleared · 1983-1988