FDA 510(k) Premarket Notification

K112165 RHEA CUP

CLEARED

May 24, 2012
301 days to decision

K112165 · Product code: **HHE** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k112165/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cup, Menstrual (HHE)
Date received	Jul 28, 2011
Decision date	May 24, 2012
Days to decision	301 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Apex Medical Technologies, Inc.**
Location	San Diego, CA, US
Contact	SCOTT HERRICK
510(k) history	8 submissions · 8 cleared · 1987-2012