FDA 510(k) Premarket Notification

K103695 PREPEX SYSTEM

CLEARED

Jan 10, 2012
389 days to decision

K103695 · Product code: **HFX** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k103695/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clamp, Circumcision (HFX)
Date received	Dec 17, 2010
Decision date	Jan 10, 2012
Days to decision	389 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Circ Medtech**
Location	Chalotte, NC, US
Contact	SHOSHANA FRIEDMAN
510(k) history	1 submissions · 1 cleared · 2012-2012