FDA 510(k) Premarket Notification

K182002 Cumulus Remover

CLEARED

Oct 23, 2018
89 days to decision

K182002 · Product code: **MQL** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k182002/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Jul 26, 2018
Decision date	Oct 23, 2018
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kitazato Corporation**
Location	Tokyo, JP
Contact	Futoshi Inoue
510(k) history	13 submissions · 13 cleared · 2017-2026