FDA 510(k) Premarket Notification

K193522 iMedium Single Step

CLEARED

Aug 25, 2020
250 days to decision

K193522 · Product code: **MQL** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k193522/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Dec 19, 2019
Decision date	Aug 25, 2020
Days to decision	250 days
Third-party review	No
Summary / Statement	Summary
Other names	iMedium Single Step with HSA; iMedium Single Step with rHA

APPLICANT

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