FDA 510(k) Premarket Notification

K234023 Oocyte Flushing & Retrieval Medium

CLEARED

May 10, 2024
142 days to decision

K234023 · Product code: **MQL** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k234023/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Dec 20, 2023
Decision date	May 10, 2024
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	Gamete Buffer

APPLICANT

Company	**Gimbo Medical Technology Shenzhen Co., Ltd.**
Location	Shenzhen, CN
Contact	Leo Guo
510(k) history	6 submissions · 6 cleared · 2024-2025