FDA 510(k) Premarket Notification

K983589 P-1 (PREIMPLANTATION STAGE ONE) MEDIUM

CLEARED

Feb 18, 1999
128 days to decision

K983589 · Product code: **MQL** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k983589/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Oct 13, 1998
Decision date	Feb 18, 1999
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Irvine Scientific Sales Co., Inc.**
Location	Santa Ana, CA, US
Contact	ROBERTA L JOHNSON
510(k) history	40 submissions · 40 cleared · 1997-2017