FDA 510(k) Premarket Notification

K984172 MODIFICATION OF PURESPERM

CLEARED

Jan 14, 1999
55 days to decision

K984172 · Product code: **MQL** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k984172/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Nov 20, 1998
Decision date	Jan 14, 1999
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nidacon International AB**
Location	Deer Field, IL, US
Contact	DANIEL KAMM
510(k) history	12 submissions · 12 cleared · 1998-2014