FDA 510(k) Premarket Notification

K022443 SPERMASSIST

CLEARED

Aug 28, 2002
34 days to decision

K022443 · Product code: **MQL** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k022443/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Jul 25, 2002
Decision date	Aug 28, 2002
Days to decision	34 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