FDA 510(k) Premarket Notification

K991264 <GENX> SINGLE LUMEN SIDEPORT NEEDLE

CLEARED

Sep 9, 1999
149 days to decision

K991264 · Product code: **MQE** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k991264/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Assisted Reproduction (MQE)
Date received	Apr 13, 1999
Decision date	Sep 9, 1999
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**<Genx> Intl., Inc.**
Location	Madison, CT, US
Contact	MICHAEL D CECCHI
510(k) history	32 submissions · 32 cleared · 1996-2012