FDA 510(k) Premarket Notification

K901512 L SOPHIA

CLEARED

Jul 20, 1990
113 days to decision

K901512 · Product code: **LHD** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k901512/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Fertility Diagnostic, Proceptive (LHD)
Date received	Mar 29, 1990
Decision date	Jul 20, 1990
Days to decision	113 days
Third-party review	No

APPLICANT

Company	**Nishitomo Co., Inc.**
Location	Japan, JP
Contact	NISHIMURA
510(k) history	2 submissions · 2 cleared · 1990-2003