FDA 510(k) Premarket Notification

K823209 BIOSELF 101

CLEARED

Feb 15, 1983
110 days to decision

K823209 · Product code: **LHD** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k823209/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Fertility Diagnostic, Proceptive (LHD)
Date received	Oct 28, 1982
Decision date	Feb 15, 1983
Days to decision	110 days
Third-party review	No

APPLICANT

Company	**Bioself, Inc.**
Location	Mchenry, IL, US
510(k) history	3 submissions · 3 cleared · 1983-1992