FDA 510(k) Premarket Notification

K925333 SINGLE USE TUNGSTEN WIRE LEE LOOP ELECTRODE

CLEARED

Sep 27, 1994
706 days to decision

K925333 · Product code: **HGI** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k925333/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocautery, Gynecologic (and Accessories) (HGI)
Date received	Oct 21, 1992
Decision date	Sep 27, 1994
Days to decision	706 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Aspen Labs**
Location	Utica, NY, US
Contact	JANE JOHNSON
510(k) history	6 submissions · 6 cleared · 1991-1997