FDA 510(k) Premarket Notification

K881312 LAMINARIA

CLEARED

May 23, 1988
56 days to decision

K881312 · Product code: **HDY** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k881312/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Cervical, Hygroscopic-laminaria (HDY)
Date received	Mar 28, 1988
Decision date	May 23, 1988
Days to decision	56 days
Third-party review	No

APPLICANT

Company	**Busse Hospital Disposables, Inc.**
Location	Mchenry, IL, US
Contact	PARTHA BASUMALLIK
510(k) history	31 submissions · 29 cleared · 1983-2012