FDA 510(k) Premarket Notification

K810697 AXISONIC II

CLEARED

Jul 13, 1981
119 days to decision

K810697 · Product code: **HDR** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k810697/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cap, Cervical (HDR)
Date received	Mar 16, 1981
Decision date	Jul 13, 1981
Days to decision	119 days
Third-party review	No

APPLICANT

Company	**Teknar, Inc.**
Location	Mchenry, IL, US
510(k) history	18 submissions · 17 cleared · 1980-1990