FDA 510(k) Premarket Notification

K913697 AUTOMATIC CORNEAL SHAPER

CLEARED

Nov 5, 1991
78 days to decision

K913697 · Product code: **HNO** · Ophthalmic
Source: https://www.510kdatabase.net/k913697/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Keratome, Ac-powered (HNO)
Date received	Aug 19, 1991
Decision date	Nov 5, 1991
Days to decision	78 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Hansa Research & Development, Inc.**
Location	Miami, FL, US
Contact	BRIGITTA HELLENKAMP
510(k) history	1 submissions · 1 cleared · 1991-1991