FDA 510(k) Premarket Notification

CLEARED

K970377 PLANCON MICROLAMELLAR KERATOME (SINGLE PIECE KERATOME HEAD WITH ACCESSORIES)

Mar 31, 1997
56 days to decision

K970377 · Product code: **HNO** · Ophthalmic
Source: https://www.510kdatabase.net/k970377/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Keratome, Ac-powered (HNO)
Date received	Feb 3, 1997
Decision date	Mar 31, 1997
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Plancon Instruments**
Location	Antony, FR
Contact	ALAIN DUPRAT
510(k) history	3 submissions · 3 cleared · 1996-1998