FDA 510(k) Premarket Notification

K980675 SUMMIT KRUMEICH-BARRAQUER MICROKERATOME

CLEARED

Dec 22, 1998
305 days to decision

K980675 · Product code: **HNO** · Ophthalmic
Source: https://www.510kdatabase.net/k980675/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Keratome, Ac-powered (HNO)
Date received	Feb 20, 1998
Decision date	Dec 22, 1998
Days to decision	305 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Summit Technology, Inc.**
Location	Waltham, MA, US
Contact	Eric Ankerud
510(k) history	5 submissions · 5 cleared · 1990-1998

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k980675/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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