

K944207 TOPOGRAPHIC MODELING SYSTEM 2 TMS-2Dec 7, 1994
100 days to decisionK944207 · Product code: **HLQ** · Ophthalmic
Source: <https://www.510kdatabase.net/k944207/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Keratoscope, Ac-powered (HLQ)
Date received	Aug 29, 1994
Decision date	Dec 7, 1994
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Computed Anatomy, Inc.
Location	New York, NY, US
Contact	CHARLES J KLEIN
510(k) history	4 submissions · 4 cleared · 1986-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944207/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026