

**K042083 MODIFICATION TO VISITOME 20-10
MICROKERATOME**Nov 16, 2004
105 days to decisionK042083 · Product code: **HNO** · Ophthalmic
Source: <https://www.510kdatabase.net/k042083/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Keratome, Ac-powered (HNO)
Date received	Aug 3, 2004
Decision date	Nov 16, 2004
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biovision AG
Location	Irvine, CA, US
Contact	DALE SADLIK
510(k) history	2 submissions · 2 cleared · 2002-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042083/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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