

K041206 EPITOME SYSTEMSep 15, 2004
131 days to decisionK041206 · Product code: **HNO** · Ophthalmic
Source: <https://www.510kdatabase.net/k041206/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Keratome, Ac-powered (HNO)
Date received	May 7, 2004
Decision date	Sep 15, 2004
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gebauer Medizintechnik GmbH
Location	Lexington, MA, US
Contact	KIMBERLEY DONEY
510(k) history	2 submissions · 2 cleared · 2004-2009

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