

**K090078 KERASYS BIOENGINEERED LAMELLAR PATCH
GRAFT**May 8, 2009
116 days to decisionK090078 · Product code: **NXM** · Ophthalmic
Source: <https://www.510kdatabase.net/k090078/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Eyelid Spacer/graft, Biologic (NXM)
Date received	Jan 12, 2009
Decision date	May 8, 2009
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Iop, Inc.
Location	Malibu, CA, US
Contact	JASON MALECKA
510(k) history	9 submissions · 8 cleared · 1989-2009

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