

**K950806 SOLID DILICONE IMPLANTS, SDILICONE SPONGE
IMPLANTS**Jun 5, 1996
469 days to decisionK950806 · Product code: **HQX** · Ophthalmic
Source: <https://www.510kdatabase.net/k950806/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Orbital, Extra-ocular (HQX)
Date received	Feb 22, 1995
Decision date	Jun 5, 1996
Days to decision	469 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mira, Inc.
Location	Waltham, MA, US
Contact	ROSINA ROBINSON
510(k) history	21 submissions · 21 cleared · 1984-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k950806/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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