

K980816 RETINAL DETACHMENT IMPLANTS, INCLUDING BANDS, STRIPS (RAILS) AND SPONGESSep 18, 1998
199 days to decisionK980816 · Product code: **HQX** · Ophthalmic
Source: <https://www.510kdatabase.net/k980816/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Orbital, Extra-ocular (HQX)
Date received	Mar 3, 1998
Decision date	Sep 18, 1998
Days to decision	199 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Fci Ophthalmics, Inc.
Location	Centercille, MA, US
Contact	ANNE BOHSACK
510(k) history	13 submissions · 13 cleared · 1996-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k980816/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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