

K970320 SCLERAL SHELLJul 7, 1997
160 days to decisionK970320 · Product code: **HQT** · Ophthalmic
Source: <https://www.510kdatabase.net/k970320/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shell, Scleral (HQT)
Date received	Jan 28, 1997
Decision date	Jul 7, 1997
Days to decision	160 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Xavier A. Guerra, Ocularist, Inc.
Location	San Antonio, TX, US
Contact	XAVIER A GUERRA
510(k) history	2 submissions · 2 cleared · 1997-1997

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