FDA 510(k) Premarket Notification

K983983 EDI VERIS SYSTEM

CLEARED

Feb 3, 1999
86 days to decision

K983983 · Product code: **HLX** · Ophthalmic
Source: https://www.510kdatabase.net/k983983/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Photostimulator, Ac-powered (HLX)
Date received	Nov 9, 1998
Decision date	Feb 3, 1999
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Electro-Diagnostic Imaging, Inc.**
Location	Los Altos, CA, US
Contact	SHEILA W PICKERING
510(k) history	2 submissions · 2 cleared · 1999-2001