FDA 510(k) Premarket Notification

K970598 INTEGRATED VISUALIZATION SYSTEM

CLEARED

Mar 12, 1997
22 days to decision

K970598 · Product code: **FCW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k970598/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Source, Fiberoptic, Routine (FCW)
Date received	Feb 18, 1997
Decision date	Mar 12, 1997
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Urohealth, Inc.**
Location	Costa Mesa, CA, US
Contact	RONALD BERGESON
510(k) history	1 submissions · 1 cleared · 1997-1997