FDA 510(k) Premarket Notification

K820008 VERSATOME I

CLEARED

Feb 22, 1982
49 days to decision

K820008 · Product code: **HQE** · Ophthalmic
Source: https://www.510kdatabase.net/k820008/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Vitreous Aspiration And Cutting, Ac-powered (HQE)
Date received	Jan 4, 1982
Decision date	Feb 22, 1982
Days to decision	49 days
Third-party review	No

APPLICANT

Company	**Alphamedix, Inc.**
Location	Mchenry, IL, US
510(k) history	7 submissions · 5 cleared · 1982-1985