FDA 510(k) Premarket Notification

K854793 MONOPOLAR INJECTION NEEDLE ELECTRODE

CLEARED

Feb 18, 1986
75 days to decision

K854793 · Product code: **HLW** · Ophthalmic
Source: https://www.510kdatabase.net/k854793/

SUBMISSION DETAILS

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Preamplifier, Battery-powered, Ophthalmic (HLW)
Date received	Dec 5, 1985
Decision date	Feb 18, 1986
Days to decision	75 days
Third-party review	No

APPLICANT

Company	**Oculinum, Inc.**
Location	Mill Valley, CA, US
Contact	SCOTT, M.D.
510(k) history	3 submissions · 2 cleared · 1986-1990