FDA 510(k) Premarket Notification

K801608 MCCULLEY CONTINUOUS SUTURE TIGHTNER

CLEARED

Aug 12, 1980
28 days to decision

K801608 · Product code: **HND** · Ophthalmic
Source: https://www.510kdatabase.net/k801608/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spatula, Ophthalmic (HND)
Date received	Jul 15, 1980
Decision date	Aug 12, 1980
Days to decision	28 days
Third-party review	No

APPLICANT

Company	**Edward Weck, Inc.**
Location	Mchenry, IL, US
510(k) history	140 submissions · 140 cleared · 1976-1992