FDA 510(k) Premarket Notification

K801937 BLEPHAROMETER

CLEARED

Sep 16, 1980
35 days to decision

K801937 · Product code: **HOE** · Ophthalmic
Source: https://www.510kdatabase.net/k801937/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Caliper, Ophthalmic (HOE)
Date received	Aug 12, 1980
Decision date	Sep 16, 1980
Days to decision	35 days
Third-party review	No

APPLICANT

Company	**Aztec Medical Products, Inc.**
Location	Mchenry, IL, US
510(k) history	5 submissions · 4 cleared · 1979-1980