FDA 510(k) Premarket Notification

K914221 KPE 220 TS, NONSTERILE

CLEARED

Oct 25, 1991
63 days to decision

K914221 · Product code: **HQE** · Ophthalmic
Source: https://www.510kdatabase.net/k914221/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Vitreous Aspiration And Cutting, Ac-powered (HQE)
Date received	Aug 23, 1991
Decision date	Oct 25, 1991
Days to decision	63 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Ipax, Inc.**
Location	CO, US
Contact	PENNELL
510(k) history	18 submissions · 18 cleared · 1984-2021