FDA 510(k) Premarket Notification

K000416 TRANSPAK (VITREORETINAL INFUSION PAK), MODELS 90000, 90001

CLEARED

May 8, 2000
90 days to decision

K000416 · Product code: **MPA** · Ophthalmic
Source: https://www.510kdatabase.net/k000416/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoilluminator (MPA)
Date received	Feb 8, 2000
Decision date	May 8, 2000
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Retinalabs.Com**
Location	Atlanta, GA, US
Contact	FRANK TIGHE
510(k) history	5 submissions · 5 cleared · 2000-2000