FDA 510(k) Premarket Notification

K212741 EZYPOR

CLEARED

Jun 24, 2022
298 days to decision

K212741 · Product code: **HPZ** · Ophthalmic
Source: https://www.510kdatabase.net/k212741/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Eye Sphere (HPZ)
Date received	Aug 30, 2021
Decision date	Jun 24, 2022
Days to decision	298 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fci (France Chirurgie Instrumentation) Sas**
Location	Paris, FR
Contact	Thierry Fetick
510(k) history	4 submissions · 4 cleared · 2020-2022

REGULATORY CONSULTANT

Consulting firm	**Clinical Research Consultants, Inc.**
Contact	Barbara S. Fant

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov