

K212741 EZYPORJun 24, 2022
298 days to decisionK212741 · 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](https://accessdata.fda.gov)

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