

K203569 Gold Tapered Weight Eyelid Implants, Platinum Tapered Weight Eyelid ImplantsJun 11, 2021
186 days to decisionK203569 · Product code: **NCB** · Ophthalmic
Source: <https://www.510kdatabase.net/k203569/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Weights, Eyelid, Implantable (NCB)
Date received	Dec 7, 2020
Decision date	Jun 11, 2021
Days to decision	186 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	Dennis Hahn

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203569/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026