

K231106 Accuject Refra Injector AR2900Sep 19, 2023
153 days to decisionK231106 · Product code: **MSS** · Ophthalmic
Source: <https://www.510kdatabase.net/k231106/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Folders And Injectors, Intraocular Lens (iol) (MSS)
Date received	Apr 19, 2023
Decision date	Sep 19, 2023
Days to decision	153 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medicel AG
Location	Hasbrouck Heights, NJ, US
Contact	Erik Braziulis
510(k) history	6 submissions · 6 cleared · 2004-2025

REGULATORY CONSULTANT

Consulting firm	Staar Surgical
Contact	Dan Lew

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/k231106/> 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 26, 2026