

K243395 MICOR 700 with Auto I/AAug 8, 2025
281 days to decisionK243395 · Product code: **HQC** · Ophthalmic
Source: <https://www.510kdatabase.net/k243395/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Phacofragmentation (HQC)
Date received	Oct 31, 2024
Decision date	Aug 8, 2025
Days to decision	281 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Carl Zeiss Meditec Cataract Technology, Inc.
Location	Reno, NV, US
Contact	Andrew Rybold
510(k) history	7 submissions · 7 cleared · 2019-2025

REGULATORY CONSULTANT

Consulting firm	GSM Services, Inc.
Contact	Gary Mocnik

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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