FDA 510(k) Premarket Notification

K242801 MICOR 700 System (N/A)

CLEARED

Jun 11, 2025
267 days to decision

K242801 · Product code: **HQC** · Ophthalmic
Source: https://www.510kdatabase.net/k242801/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Phacofragmentation (HQC)
Date received	Sep 17, 2024
Decision date	Jun 11, 2025
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	MICOR 700 drive (FG-50631); MICOR 700 extractor (FG-50621); MICOR 700 vitrector (FG-51185)

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**
Contact	Gary Mocnik

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