

K233398 Faros Surgical SystemJun 27, 2024
268 days to decisionK233398 · Product code: **HQC** · Ophthalmic
Source: <https://www.510kdatabase.net/k233398/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Unit, Phacofragmentation (HQC) |
| Date received | Oct 3, 2023 |
| Decision date | Jun 27, 2024 |
| Days to decision | 268 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Oertli Instrumente AG |
| Location | Berneck, CH |
| Contact | Marianne Kesseli |
| 510(k) history | 2 submissions · 2 cleared · 2014-2024 |

REGULATORY CONSULTANT

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|-----------------|--|
| Consulting firm | CardioMed Device Consultants, LLC |
| Contact | Meagan Fagan |

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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