

K192778 Kinos Axiom Total Ankle SystemJun 30, 2020
274 days to decisionK192778 · Product code: **HSN** · Orthopedic
Source: <https://www.510kdatabase.net/k192778/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Ankle, Semi-constrained, Cemented, Metal/polymer (HSN) |
| Date received | Sep 30, 2019 |
| Decision date | Jun 30, 2020 |
| Days to decision | 274 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Kinos Medical |
| Location | Wayne, PA, US |
| Contact | Brian Garvey |
| 510(k) history | 1 submissions · 1 cleared · 2020-2020 |

REGULATORY CONSULTANT

| | |
|-----------------|------------------------|
| Consulting firm | Alyssa Schwartz |
| Contact | Alyssa Schwartz |

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/k192778/> 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 June 28, 2026