

K943354 SUTTER HAMMERTOES JOINT PROSTHESISJun 12, 1995
335 days to decisionK943354 · Product code: **KWH** · Orthopedic
Source: <https://www.510kdatabase.net/k943354/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Toe, Constrained, Polymer (KWH) |
| Date received | Jul 12, 1994 |
| Decision date | Jun 12, 1995 |
| Days to decision | 335 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Sutter Corp. |
| Location | San Diego, CA, US |
| Contact | LOUISE FOCHT |
| 510(k) history | 7 submissions · 7 cleared · 1989-1995 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k943354/> 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 21, 2026