

K223095 Senhance Surgical SystemMar 16, 2023
167 days to decisionK223095 · Product code: **NAY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k223095/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Surgical, Computer Controlled Instrument (NAY) |
| Date received | Sep 30, 2022 |
| Decision date | Mar 16, 2023 |
| Days to decision | 167 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Asensus Surgical, Inc. |
| Location | Durham, NC, US |
| Contact | Casey Hinckley |
| 510(k) history | 5 submissions · 5 cleared · 2021-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223095/> 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 26, 2026