

K193256 Anjon Bremer Halo SystemMar 2, 2020
97 days to decisionK193256 · Product code: **JEC** · Orthopedic
Source: <https://www.510kdatabase.net/k193256/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Component, Traction, Invasive (JEC) |
| Date received | Nov 26, 2019 |
| Decision date | Mar 2, 2020 |
| Days to decision | 97 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Anjon Holdings, LLC |
| Location | Jacksonville, FL, US |
| Contact | Kenneth A Collins |
| 510(k) history | 2 submissions · 2 cleared · 2018-2020 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193256/> 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