

K192349 Bactisure Wound LavageJan 23, 2020
147 days to decisionK192349 · Product code: **FQH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192349/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Lavage, Jet (FQH) |
| Date received | Aug 29, 2019 |
| Decision date | Jan 23, 2020 |
| Days to decision | 147 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Next Science, LLC |
| Location | Jacksonville, FL, US |
| Contact | Jeanne Lee |
| 510(k) history | 6 submissions · 6 cleared · 2015-2021 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192349/> 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