

**K220964 VERSAJET Hydrosurgery System (III)**May 16, 2023  
410 days to decisionK220964 · Product code: **FQH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k220964/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Lavage, Jet (FQH)                  |
| Date received         | Apr 1, 2022                        |
| Decision date         | May 16, 2023                       |
| Days to decision      | 410 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Smith &amp; Nephew Medical Limited</b> |
| Location       | Hull, GB                                  |
| Contact        | Zoe Smith                                 |
| 510(k) history | 20 submissions · 20 cleared · 2016-2024   |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220964/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026