

**K935496 NANOSEP N10**Apr 26, 1994  
162 days to decisionK935496 · Product code: **JJH** · Chemistry  
Source: <https://www.510kdatabase.net/k935496/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Clinical Sample Concentrator (JJH) |
| Date received         | Nov 15, 1993                       |
| Decision date         | Apr 26, 1994                       |
| Days to decision      | 162 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Intersep , Ltd.</b>                |
| Location       | England, GB                           |
| Contact        | RICHARD HICKS                         |
| 510(k) history | 1 submissions · 1 cleared · 1994-1994 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k935496/> 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 July 1, 2026