

K963748 BIO-PLEXUS DROP-IT NEEDLE HOLDERJun 6, 1997
262 days to decisionK963748 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k963748/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Needle, Hypodermic, Single Lumen (FMI) |
| Date received | Sep 17, 1996 |
| Decision date | Jun 6, 1997 |
| Days to decision | 262 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Bio-Plexus, Inc. |
| Location | Tolland, CT, US |
| Contact | CARL R SAHI |
| 510(k) history | 6 submissions · 6 cleared · 1990-2001 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k963748/> 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 29, 2026