

**K852442 PHARMA-PLAST NEEDLE**Sep 20, 1985  
102 days to decisionK852442 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k852442/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | Needle, Hypodermic, Single Lumen (FMI) |
| Date received         | Jun 10, 1985                           |
| Decision date         | Sep 20, 1985                           |
| Days to decision      | 102 days                               |
| Third-party review    | No                                     |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Pharma-Plast USA, Inc.</b>         |
| Location       | Canada H3a 2n4, CA                    |
| Contact        | DOUGLAS M BENNETT                     |
| 510(k) history | 9 submissions · 9 cleared · 1985-1989 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k852442/>; 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 27, 2026