

**K973103 CHARTERMED TPN-EVA BAGS**Nov 24, 1997  
97 days to decisionK973103 · Product code: **KPE** · General Hospital  
Source: <https://www.510kdatabase.net/k973103/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Container, I.v. (KPE)              |
| Date received         | Aug 19, 1997                       |
| Decision date         | Nov 24, 1997                       |
| Days to decision      | 97 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Chartermed, Inc.</b>               |
| Location       | Lakewood, NJ, US                      |
| Contact        | K. ALICE PREVILLE                     |
| 510(k) history | 4 submissions · 4 cleared · 1990-1997 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973103/> 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 2, 2026