

**K801021 URINEBAG**Jul 28, 1980  
89 days to decisionK801021 · Product code: **KNX** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k801021/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                |
| Submission type       | Traditional   |
| Device classification | Collector, Urine, (and Accessories) For Indwelling Catheter (KNX) |
| Date received         | Apr 30, 1980  |
| Decision date         | Jul 28, 1980  |
| Days to decision      | 89 days   |
| Third-party review    | No  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Unovex of Denmark</b>              |
| Location       | Mchenry, IL, US                       |
| 510(k) history | 1 submissions · 1 cleared · 1980-1980 |

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k801021/> 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 4, 2026