

**K180708 Entuit LP Gastrostomy BR Low Profile Balloon Retention Feeding Tube, Entuit LP Gastrostomy BR Low Profile Balloon Retention Feeding Tube with ENFit Connection, Entuit LP Patient Care Kit, Entuit LP Patient Care Kit with ENFit Connection, PromaX Low Profile Gastrostomy Feeding Tube, PromaX LP Patient Care Kit with ENFit**

Oct 18, 2018  
213 days to decision

K180708 · Product code: **PIF** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k180708/>

**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent - K                                  |
| Submission type       | Traditional   |
| Device classification | Gastrointestinal Tubes With Enteral Specific Connectors (PIF) |
| Date received         | Mar 19, 2018  |
| Decision date         | Oct 18, 2018  |
| Days to decision      | 213 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|--|
| Company        | <b>Xeridiam Medical Devices, A Spectrum Plastics Group Company</b> |
| Location       | Tucson, AZ, US   |
| Contact        | Steve Murray   |
| 510(k) history | 2 submissions · 1 cleared · 2018-2023                              |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k180708/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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