

**K971434 A.M.T. G-TUBE BALLOON REPLACEMENT  
GASTROSTOMY FEEDING DEVICE**Aug 17, 1998  
486 days to decisionK971434 · Product code: **KNT** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k971434/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)              |
| Submission type       | Traditional                                     |
| Device classification | Tubes, Gastrointestinal (and Accessories) (KNT) |
| Date received         | Apr 18, 1997                                    |
| Decision date         | Aug 17, 1998                                    |
| Days to decision      | 486 days  |
| Third-party review    | No  |
| Summary / Statement   | Statement                                       |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Applied Medical Technologies</b>     |
| Location       | Mchenry, IL, US                         |
| Contact        | THOMAS W PARKINSON                      |
| 510(k) history | 23 submissions · 20 cleared · 1981-1998 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971434/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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