

**K042580 TIDI BRAND STERILIZATION WRAP**Nov 17, 2004  
56 days to decisionK042580 · Product code: **FRG** · General Hospital  
Source: <https://www.510kdatabase.net/k042580/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Sep 22, 2004
Decision date	Nov 17, 2004
Days to decision	56 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Banta Healthcare Group, Ltd.</b>
Location	Clearwater, FL, US
Contact	INA GORDON
510(k) history	2 submissions · 2 cleared · 1998-2004

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042580/> 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