

**K003749 100% 30G POLYPROPYLENE SPUNBOND ISLATION  
GROWN**Feb 23, 2001  
81 days to decisionK003749 · Product code: **FYC** · General Hospital  
Source: <https://www.510kdatabase.net/k003749/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Dec 4, 2000
Decision date	Feb 23, 2001
Days to decision	81 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Banta Healthcare</b>
Location	Crofton, MD, US
Contact	YOLNDA SMITH
510(k) history	1 submissions · 1 cleared · 2001-2001

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003749/>; 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