

**K082387 APOGEE AND PERIGEE SYSTEMS WITH INTEPRO
LITE AND INTEXEN LP, PART OF THE AMS**Dec 4, 2008
107 days to decisionK082387 · Product code: **OTP** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k082387/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Pelvic Organ Prolapse, Transvaginally Placed (OTP)
Date received	Aug 19, 2008
Decision date	Dec 4, 2008
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary
Other names	PELVIC FLOOR REPAIR SYSTEM

APPLICANT

Company	American Medical Systems
Location	Minnetonka, MN, US
Contact	SARAH PETERSON
Website	http://www.varian.com
510(k) history	10 submissions · 10 cleared · 2008-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k082387/> Data sourced from FDA 510(k) public records (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. - Generated June 6, 2026