K121612 ELEVATE PROLAPSE REPAIR SYSTEMS-APICAL NEEDLE PASSER SHEATH MODIFICATION

CLEARED

Jul 20, 2012
49 days to decision

K121612 · Product code: **OTP** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k121612/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Pelvic Organ Prolapse, Transvaginally Placed (OTP)
Date received	Jun 1, 2012
Decision date	Jul 20, 2012
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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