CLEARED

K082730 AMS ELEVATE APICAL AND POSTERIOR PROLAPSE REPAIR SYSTEM WITH INTEPRO LITE, AMS ELEVATE APICAL AND POSTERIOR PROLAPSE

Nov 26, 2008
69 days to decision

K082730 · Product code: **OTP** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k082730/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Pelvic Organ Prolapse, Transvaginally Placed (OTP)
Date received	Sep 18, 2008
Decision date	Nov 26, 2008
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**American Medical Systems, Inc.**
Location	Mchenry, IL, US
Contact	MONA INMAN
510(k) history	72 submissions · 72 cleared · 1979-2013