



[FDA Home Page](#) | [CDRH Home Page](#) | [Search](#) | [CDRH A-Z Index](#) | [Contact CDRH](#)



[510\(k\)](#) | [Registration](#) | [Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)
[CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [Recalls](#) | [Guidance](#) | [Standards](#)

[New Search](#)

[Back To Search Results](#)

510(k) Premarket Notification Database

Device Classification Name [Suture, Nonabsorbable, Synthetic, Polypropylene](#)

510(K) Number K070243

Regulation Number [878.5010](#)

Device Name SUTRALENE POLYPROPYLENE SUTURES

Applicant VISIONARY MEDICAL SUPPLIES, INC.
800 Levanger Ln.
Stoughton, WI 53589

Contact Gary Syring

Classification Product Code [GAW](#)

Date Received 01/25/2007

Decision Date 04/17/2007

Decision Substantially Equivalent (SE)

Classification Advisory Committee General & Plastic Surgery

Review Advisory Committee General & Plastic Surgery

Statement/Summary/Purged Status Summary Only

Summary [Summary](#)

Type Abbreviated

Reviewed By Third Party No

Expedited Review No