

510(k) Premarket Notification

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Device Classification Name	Gown, Surgical
510(K) Number	K110724
Device Name	SURGICAL PROCEDURE PACKS
Applicant	OMNIA SPA 11460 N Meridian Street Suite 150 Carmel, IN 46032
Applicant Contact	Jamie Austin
Correspondent	OMNIA SPA 11460 N Meridian Street Suite 150 Carmel, IN 46032
Correspondent Contact	Jamie Austin
Regulation Number	878.4040
Classification Product Code	FYA
Subsequent Product Codes	FXX KKX LRO
Date Received	03/16/2011
Decision Date	06/23/2011
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General & Plastic Surgery
510k Review Panel	General Hospital
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No