

Device Classification Name	elastomer, silicone block
510(k) Number	K042054
Device Name	SILIMED PECTORAL IMPLANT SILIMED, INC.
Applicant	po box 4341 crofton, MD 21114
Contact	e.j. smith
Regulation Number	874.3620
Classification Product Code	MIB
Date Received	08/04/2004
Decision Date	02/23/2005
Decision	substantially equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery
Type	Traditional
Reviewed by Third Party	No
Expedited Review	No