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510(K) SUMMARY
(as required by 807.92(c))

K961773

Submitter of 510(k): Regulatory & Marketing Services, Inc. (RMS)
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Date of Summary: May 6, 1996

Trade Name: Protec Sterile Gauze Sponge

Classification Name: Gauze Sponge

Predicate Device: Keilei International K895086

Device Description/ DeGasa USP Gauze are sterile gauze sponges that are made with 100 % cotton, and are in the form of plain woven cloth conforming to the specifications of USP type VII.

Comparison:	Protec	Keilei
	Threads per 2.54 cm Warp	Same
	Threads per 2.54 cm Filling	Same
	Avg. count per 6.45 sq. cm	Same
	Weight: g per sq. meter	Same

Intended Use: DeGasa Sterile USP Gauze Sponges are used in a hospital setting where sterile gauze is required. The instructions for use by physicians using gauze sponges are exactly the same as the instructions for use found on present labeling for similar products currently on the market.