FDA 510(k) Premarket Notification

K920355 SPECIALTY SPONGES

CLEARED

Aug 6, 1992
192 days to decision

K920355 · Product code: **GDY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k920355/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze/sponge, Internal, X-ray Detectable (GDY)
Date received	Jan 27, 1992
Decision date	Aug 6, 1992
Days to decision	192 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Ultracell Medical Technologies, Inc.**
Location	North Stonington, CT, US
Contact	GEORGE P KORTEWEG
510(k) history	24 submissions · 24 cleared · 1992-2001