

K950370 ULTRACELL ORTHOPEDIC SPONGESApr 17, 1995
76 days to decisionK950370 · Product code: **GDY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k950370/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze/sponge, Internal, X-ray Detectable (GDY)
Date received	Jan 31, 1995
Decision date	Apr 17, 1995
Days to decision	76 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k950370/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026