

K920356 SURGICAL SPONGESAug 6, 1992
192 days to decisionK920356 · Product code: **GDY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k920356/>**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 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k920356/> 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