

K882708 GAUZE SPONGE, X-RAY DETECTABLEAug 3, 1988
37 days to decisionK882708 · Product code: **GDY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k882708/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Gauze/sponge, Internal, X-ray Detectable (GDY) |
| Date received | Jun 27, 1988 |
| Decision date | Aug 3, 1988 |
| Days to decision | 37 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Bioseal |
| Location | Brea, CA, US |
| Contact | WILLIAM L RUNION |
| 510(k) history | 10 submissions · 10 cleared · 1988-1989 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k882708/>; 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 May 27, 2026