

**K013059 STONY BROOK SURGICAL INNOVAIONS STERNA-
WIRE (STERNAL SUTURES)**

Oct 22, 2001
41 days to decision

K013059 · Product code: **GAQ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k013059/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Suture, Nonabsorbable, Steel, Monofilament And Multifilament, Sterile (GAQ) |
| Date received | Sep 11, 2001 |
| Decision date | Oct 22, 2001 |
| Days to decision | 41 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Stony Brook Surgical Innovations, Inc. |
| Location | Great Neck, NY, US |
| Contact | SUSAN D GOLDSTEIN-FALK |
| 510(k) history | 2 submissions · 2 cleared · 1993-2001 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k013059/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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