

**K100418 SUPERIOR STARBURST REUSABLE SELF-ADHERING
TENS/NMES/FES STIMULATING ELECTRODE**Sep 3, 2010
199 days to decisionK100418 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k100418/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrode, Cutaneous (GXY) |
| Date received | Feb 16, 2010 |
| Decision date | Sep 3, 2010 |
| Days to decision | 199 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Covidien |
| Location | North Haven, CT, US |
| Contact | WING NG |
| 510(k) history | 130 submissions · 126 cleared · 2008-2024 |

Covidien is an Irish-registered global healthcare products company headquartered in North Haven, Connecticut. Now part of Medtronic following a 2015 acquisition, the brand continues to operate as a major medical device manufacturer. Covidien maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions spanning 2008 to 2024. The company specializes in General & Plastic Surgery devices, with a dominant focus on surgical staplers, sutures, and wound closure systems. Recent clearances include advanced stapling technologies, endotracheal tubes, a...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k100418/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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