

K222641 Signia™ Small Diameter Reloads Including Regular (Round) Tip Version

Nov 29, 2022
89 days to decisionK222641 · Product code: **GDW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k222641/>

SUBMISSION DETAILS

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Staple, Implantable (GDW) |
| Date received | Sep 1, 2022 |
| Decision date | Nov 29, 2022 |
| Days to decision | 89 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Covidien |
| Location | North Haven, CT, US |
| Contact | Robert Zott |
| 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...

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