

K022416 CONTREET FOAM ADHESIVE/NON-ADHESIVEFeb 3, 2003
194 days to decisionK022416 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k022416/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dressing, Wound, Drug (FRO) |
| Date received | Jul 24, 2002 |
| Decision date | Feb 3, 2003 |
| Days to decision | 194 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Coloplast Corp. |
| Location | Marietta, GA, US |
| Contact | ELIZABETH BOOTS |
| 510(k) history | 54 submissions · 47 cleared · 1985-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k022416/> 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 28, 2026