

K991202 MODIFICATION TO WOUND'DRESJun 4, 1999
74 days to decisionK991202 · Product code: **MGQ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k991202/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dressing, Wound And Burn, Hydrogel W/drug And/or Biologic (MGQ) |
| Date received | Mar 22, 1999 |
| Decision date | Jun 4, 1999 |
| Days to decision | 74 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k991202/> 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