

K093320 DRYODINE CADEXOMER-IODINE GELJun 18, 2010
238 days to decisionK093320 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k093320/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dressing, Wound, Drug (FRO) |
| Date received | Oct 23, 2009 |
| Decision date | Jun 18, 2010 |
| Days to decision | 238 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Collegium Pharmaceutical Incorporated |
| Location | Cumberland, RI, US |
| Contact | MARK W TRUMBORE |
| 510(k) history | 3 submissions · 3 cleared · 2009-2010 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k093320/> 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 21, 2026