

**K971597 COMFEEL PURILON GEL,15G(3900)/COMFEEL
PURILON GEL,25G(3903)**Jul 29, 1997
89 days to decisionK971597 · Product code: **NAE** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k971597/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Hydrogel Without Drug And/or Biologic (NAE)
Date received	May 1, 1997
Decision date	Jul 29, 1997
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Coloplast Corp.
Location	Marietta, GA, US
Contact	RICHARD A HAMER
510(k) history	54 submissions · 47 cleared · 1985-2025

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