

**K221218 Silverlon Wound Contact, Burn Contact Dressings**Oct 26, 2022  
182 days to decisionK221218 · Product code: **FRO** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k221218/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Apr 27, 2022
Decision date	Oct 26, 2022
Days to decision	182 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Argentum Medical, Inc.</b>
Location	Geneva, IL, US
Contact	Kathy Herzog
510(k) history	1 submissions · 1 cleared · 2022-2022

**CLINICAL EVIDENCE - NCT04238728****Silverlon to Reduce Radiation Dermatitis**

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Status	Completed
Enrollment	31 patients (actual)
Study sites	1 site
Condition studied	Radiation Dermatitis
Primary purpose	Supportive_care
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Mar 25, 2022
Sponsor	University of Rochester (Other)

**Primary outcome**

Number of Participants With an Adverse Skin Event

**Secondary outcome**

Number of Participants With Each Grade of the Radiation Therapy Oncology Group (RTOG) Toxicity Score

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT04238728](https://clinicaltrials.gov/study/NCT04238728)