

**K231953 Biatain Fiber Ag (33570 - 5 cm x 5 cm / 2 in x 2 in)**Mar 22, 2024  
266 days to decisionK231953 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k231953/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Jun 30, 2023
Decision date	Mar 22, 2024
Days to decision	266 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Biatain Fiber Ag (33572 - 10 cm x 12 cm / 4 in x 5 in); Biatain Fiber Ag (33574 - 15 cm x 15 cm / 6 in x 6 in); Biatain Fiber Ag (33576 - 2.5 cm x 46 cm / 1 in x 18 in); Biatain Fiber Ag (33578 - 20 cm x 30 cm / 8 in x 12 in)

**APPLICANT**

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Company	<b>Coloplast Corp.</b>
Location	Marietta, GA, US
Contact	Laura Kelly
510(k) history	54 submissions · 47 cleared · 1985-2025

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