

K182681 AC5 Topical GelDec 14, 2018
79 days to decisionK182681 · Product code: **FRO** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k182681/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Sep 26, 2018
Decision date	Dec 14, 2018
Days to decision	79 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Arch Therapeutics, Inc.
Location	Framingham, MA, US
Contact	Terrence W. Norchi
510(k) history	2 submissions · 2 cleared · 2018-2020

CLINICAL EVIDENCE - NCT02704104

Safety and Performance Evaluation of the Topical Hemostatic Device (AC5™) Following Excision of Skin Lesions

Status	Completed
Enrollment	46 patients (actual)
Study sites	1 site
Condition studied	Skin Neoplasms
Primary purpose	Supportive_care
Study type	Interventional
Study design	Parallel
Masking	Single blind
Completion date	Jun 1, 2016
Sponsor	Arch Therapeutics (Industry)

Primary outcome

Number of Participants With Treatment-emergent Adverse Events Related to Clinical Investigation Product During the 30 Days of Follow-up

Secondary outcome

Median Time to Hemostasis (Seconds)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02704104