

K171191 Hexagen DermAug 25, 2017
123 days to decisionK171191 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k171191/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Apr 24, 2017
Decision date	Aug 25, 2017
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Global Health Solutions, LLC
Location	Rome, GA, US
Contact	Bradley Burnam
510(k) history	2 submissions · 2 cleared · 2016-2017

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