

**K190742 EPIFLO-28**Dec 13, 2019  
266 days to decisionK190742 · Product code: **KPJ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k190742/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Chamber, Oxygen, Topical, Extremity (KPJ)
Date received	Mar 22, 2019
Decision date	Dec 13, 2019
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

Company	<b>Neogenix, LLC Db a Ogenix</b>
Location	Beachwood, OH, US
Contact	Srinivasan Sarangapani
510(k) history	1 submissions · 1 cleared · 2019-2019

**CLINICAL EVIDENCE - NCT01291160****Transdermal Continuous Oxygen Therapy for Diabetic Foot Ulcers**

Status	Completed
Enrollment	130 patients (actual)
Study sites	14 sites
Condition studied	Diabetic Foot Ulcers
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Triple
Completion date	Feb 1, 2013
Sponsor	Neogenix, LLC db a Ogenix (Industry)

**Primary outcome****Number of 100% Wound Closure**Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT01291160](https://clinicaltrials.gov/study/NCT01291160)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190742/> Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine).  
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