

**K182582 Oryum and Ovem Epidermal Deri Prick Test Applicator**Apr 10, 2019  
203 days to decisionK182582 · Product code: **SCL** · General Hospital  
Source: <https://www.510kdatabase.net/k182582/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Allergen And Vaccine Delivery Needles (SCL)
Date received	Sep 19, 2018
Decision date	Apr 10, 2019
Days to decision	203 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Allergy &amp; Applicator Depot, LLC</b>
Location	Sound Beach, NY, US
Contact	Steve Tramontano
510(k) history	1 submissions · 1 cleared · 2019-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Contract In-House Counsel and Consultants, LLC (FDA Atty)</b>
Contact	Marc C. Sanchez

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182582/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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