



Premarket Approval (PMA)



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Note: this medical device has supplements. The device description may have changed. Be sure to look at the supplements to get an up-to-date view of this device.

Trade Name APLIGRAF (GRAFTSKIN)
Classification Name [Dressing, Wound And Burn, Interactive](#)²⁴
Generic Name Graftskin
Applicant ORGANOGENESIS, INC.
PMA Number P950032
Date Received 10/04/1995
Decision Date 05/22/1998
Conversion Date 08/08/2013
Product Code MGR [[Registered Establishments With MGR](#)²⁵]
Docket Number 98M-0992
Notice Date 12/17/1998
Advisory Committee General & Plastic Surgery
Expedited Review Granted? Yes
Combination Product [Yes](#)²⁶

Information About: [Labeling, Approval Order, Summary Of Safety And Effectiveness](#)²⁷
Recalls

[CDRH Recalls](#)²⁸

Approval Order Statement

This device is indicated for use with standard therapeutic compression for the treatment of non-infected partial and full-thickness skin ulcers due to venous insufficiency of greater than 1 month duration and which have not adequately responded to conventional ulcer therapy.

Approval Order

[Approval Order](#)²⁹

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