

510(k) Premarket Notification

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Device Classification Name	Implant, Endosseous, Root-Form
510(k) Number	K150363
Device Name	NOVA Dental Implants System
Applicant	Nova Implants, Ltd. 5 Yoni Nethanyhu St. Or Yehuda, IL 6037603
Applicant Contact	Dan Grimberg
Correspondent	Sterling Medical Registration 22817 Ventura Blvd. Woodland Hills, CA 91364
Correspondent Contact	Daniela Levy
Regulation Number	872,3640
Classification Product Code	DZE
Subsequent Product Code	NHA
Date Received	02/12/2015
Decision Date	06/29/2015
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Dental
510k Review Panel	Dental
Summary	Summary
Type	Traditional
Reviewed by Third Party	No
Combination Product	No
Predetermined Change Control Plan Authorized	No