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Device Classification under Section 513(f)(2)(de novo)



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Device Classification Name	Parathyroid Autofluorescence Imaging Device ²²
De Novo Number	DEN170092
Device Name	Fluobeam 800 Clinic Imaging Device Used With Fluocase 800 Control System
Requester	Fluoptics 7 Parvis Louis Neel Cs 20050 Grenoble Cedex 9, FR 38040
Contact	Odelie Allard
Regulation Number	878.4550 ²³
Classification Product Code	QDG ²⁴
Date Received	12/22/2017
Decision Date	11/02/2018
Decision	Granted (DENG)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery
Reclassification Order	Reclassification Order ²⁵
FDA Review	Decision Summary ²⁶
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