

510(k) Premarket Notification



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Device Classification Name [Solid State X-Ray Imager \(Flat Panel/Digital Imager\)](#)²²
510(K) Number K170480
Device Name Models 3543A, 4343A, 2929A And A843B
Applicant Shanghai PZ Medical Technolgoy Co., Ltd.
 5F, Building 13 No.2 Suide Road
 Shanghai, CN 200331
Applicant Contact Jeff Moeller
Correspondent OrganizeUS, Inc.
 8317 Lakeside Drive
 Downers Grove, IL 60516
Correspondent Contact Jeff Moeller
Regulation Number [892.1680](#)²³
Classification Product Code [MQB](#)²⁴
Date Received 02/16/2017
Decision Date 07/07/2017
Decision Substantially Equivalent (SESE)
Regulation Medical Specialty Radiology
510k Review Panel Radiology
Summary [Summary](#)²⁵
Type Traditional
Reviewed By Third Party No
Combination Product No



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