

FDA Home³ Medical Devices⁴ Databases⁵

Premarket Notification

6510(k)⁷|DeNovo⁸|Registration & Adverse |Recalls¹¹|PMA¹²|HDE¹³|Classification¹⁴|Standards¹⁵

Listing⁹ Events¹⁰ CFR Title 21¹⁶Radiation-Emitting Products¹⁷X-Ray Assembler¹⁸Medsun Reports¹⁹CLIA²⁰TPLC²¹

New Search Back To Search Results

Device

Classification Respirator, Surgical²²

Name

510(k) Number K141876

Pasture F550S Surgical N95 Respirator, Pasture F550CS Surgical N95 Respirator, Pasture **Device Name**

A520S Surgical N95 Respirator, Pasture A520CS Surgical N95 Respirator, Pasture E520S

Surgical N95 Respirator, Pasture E520CS Surgical N95 Respirator

PASTURE PHARMA PTE LTD **Applicant**

38129 SPRING CANYON DRIVE

Murrieta, CA 92563

Applicant Contact Sarah Hassan

Correspondent PASTURE PHARMA PTE LTD

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Correspondent

Sarah Hassan Contact

Regulation Number 878.4040²³

Classification MSH²⁴

Product Code

07/11/2014 **Date Received Decision Date** 10/28/2015

Decision Substantially Equivalent (SESE)

Regulation Medical

Specialty

General & Plastic Surgery

510k Review Panel General Hospital Summary²⁵ **Summary Traditional Type**

Reviewed By Third

Party

No

Combination

No **Product**

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