

510(k) Premarket Notification



[New Search](#)

[Back To Search Results](#)

Device Classification Name	Device, Counter-Pulsating, External ²¹
510(K) Number	K130439
Models	P-ECM/TM, P-ECP/TI
Device Name	EXTERNAL COUNTERPULSATION DEVICE WITH SP02 MORNITORING
Original Applicant	CHONGQING PSK SCI-TECH DEVELOPMENT CO., LTD 05c. Fuhai Kangle Building Nanshan District Shenzhen, China Shenzhen, Guangdong,
Original Contact	Field Fu
Regulation Number	870.5225 ²²
Classification Product Code	DRN ²³
Date Received	04/15/2013
Decision Date	12/12/2013
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Cardiovascular
Review Advisory Committee Type	Cardiovascular Traditional
Reviewed By Third Party	No
Expedited Review	No
Combination Product	No

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/MedicalDevices/default.htm>
5. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>
6. </scripts/cdrh/devicesatfda/index.cfm>
7. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
8. </scripts/cdrh/cfdocs/cfRL/rl.cfm>
9. </scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>
10. </scripts/cdrh/cfdocs/cfRES/res.cfm>
11. </scripts/cdrh/cfdocs/cfPMA/pma.cfm>
12. </scripts/cdrh/cfdocs/cfPCD/classification.cfm>
13. </scripts/cdrh/cfdocs/cfStandards/search.cfm>
14. </scripts/cdrh/cfdocs/cfTPLC/inspect.cfm>
15. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>
16. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
17. </scripts/cdrh/cfdocs/cfAssem/assembler.cfm>
18. </scripts/cdrh/cfdocs/Medsun/searchReportText.cfm>
19. </scripts/cdrh/cfdocs/cfClia/Search.cfm>
20. </scripts/cdrh/cfdocs/cfTPLC/tplc.cfm>

21. /scripts/cdrh/cfdocs/cfpd/classification.cfm?start_search=1&productcode=DRN
22. /scripts/cdrh/cfdocs/cfcr/cfrsearch.cfm?fr=870.5225
23. /scripts/cdrh/cfdocs/cfpd/classification.cfm?start_search=1&productcode=DRN

Page Last Updated: 12/23/2013

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

[Accessibility Contact](#) [FDA Careers](#) [FDA Basics](#) [FOIA No Fear Act](#) [Site Map](#) [Transparency Website Policies](#)

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)

[Email FDA](#)



[For Government](#) [For Press](#)

[Combination Products](#) [Advisory Committees](#) [Science & Research](#) [Regulatory Information](#) [Safety](#) [Emergency Preparedness](#) [International Programs](#) [News & Events](#) [Training and Continuing Education](#) [Inspections/Compliance](#) [State & Local Officials](#) [Consumers](#) [Industry Health Professionals](#) [FDA Archive](#)



U.S. Department of **Health & Human Services**

Links on this page: