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Device Classification Name	Oximeter[22]
510(K) Number	K173123
Device Name	Pulse Oximeter
Applicant	Shenzhen IMDK Medical Technology Co., Ltd. C Zone, 10F, Building 16, Yuanshan Industrial B Area Gongming Street Guangming District, Shenzhen, CN
Applicant Contact	Xia Yuan
Correspondent	Chonconn Medical Device Consulting Co., Ltd. 22A, Haijing Square No. 18, Taizi Road Nanshan District, Shenzhen, CN 518067
Correspondent Contact	Kevin Wang
Regulation Number	870.2700[23]
Classification Product Code	DQA[24]
Date Received	09/29/2017
Decision Date	08/13/2018
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Cardiovascular
510k Review Panel	Anesthesiology
Summary	Summary[25]
Type	Traditional
Reviewed By Third Party	No
Combination Product	No