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510(k) Premarket Notification



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Device Classification Name	System, Measurement, Blood-Pressure, Non-Invasive ²²
510(k) Number	K241351
Device Name	Blood Pressure Monitor (TMB-2092-G)
Applicant	Guangdong Transtek Medical Electronics Co., Ltd. Zone A, No. 105, Dongli Road, Torch Development District Zhongshan, CN 528437
Applicant Contact	Fan Jerry
Correspondent	Guangdong Transtek Medical Electronics Co., Ltd. Zone A, No. 105, Dongli Road, Torch Development District Zhongshan, CN 528437
Correspondent Contact	Fan Jerry
Regulation Number	870.1130 ²³
Classification Product Code	DXN ²⁴
Date Received	05/13/2024
Decision Date	08/21/2024
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Cardiovascular
510k Review Panel	Cardiovascular
Summary	Summary ²⁵
Type	Special
Reviewed by Third Party	No
Combination Product	No
Predetermined Change Control Plan Authorized	No

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