

SUMMARY OF:

P010031/S329

Concerto ICD Models C154DWK, C164AWK; Concerto II CRT-D Model D274TRK; Consulta DF4 ICD Model D204TRM; InSync II Protect ICD Model 7295; InSync III Marquis ICD Model 7279; InSync Maximo ICD Models 7304, 7303; InSync Sentry Models 7297, 7299; InSync II Marquis Model 7289; InSync Marquis Model 7277; Maximo II CRT-D Models D264TRM, D284TRK; Protecta CRT-D Models D334TRG, D334TRM; Protecta XT CRT-D Models D314TRG, D314TRM

P980016/S376

EnTrust ICD Models D154VRC, D154ATG, D154DRG; GEM II DR ICD Model 7273; GEM II VR ICD Model 7229; GEM III DR ICD Model 7275; GEM III VR ICD Model 7231; Intrinsic 30 ICD Model 7287; Intrinsic ICD Model 7288; Marquis DR ICD Model 7274; Marquis VR ICD Models 7230Cx, 7230E, 7230B; Maximo DR ICD Model 7279; Maximo II ICD Model 7278; Maximo II ICD Models D264DRM, D264VRM, D284DRG, D284VRC; Maximo VR ICD Models 7232Cx, 7232B, 7232E; Protecta ICD Models D334DRG, D334DRM, D334VRG, D334VRM; Protecta XT ICD Models D314DRG, D314DRM, D314VRG, D314VRM; Secura ICD Models D204DRM, D204VRM, D224DRG, D224VRC; Virtuoso ICD Models D154AWG, D154VWC; Virtuoso II DR/VR ICD Models D274DRG, D274VRC

P980050/S076

Gem III AT Model 7276

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**Medtronic, Inc.
8200 Coral Sea Street
Moundsview, MN 55112**

BACKGROUND/REASON FOR SUPPLEMENT

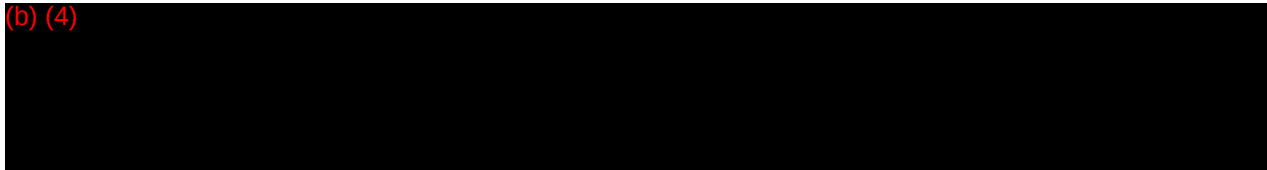
The 180-day PMA/S (subject file) was submitted by Medtronic (the company) for requesting the approval of the (b) (4)

INDICATIONS FOR USE

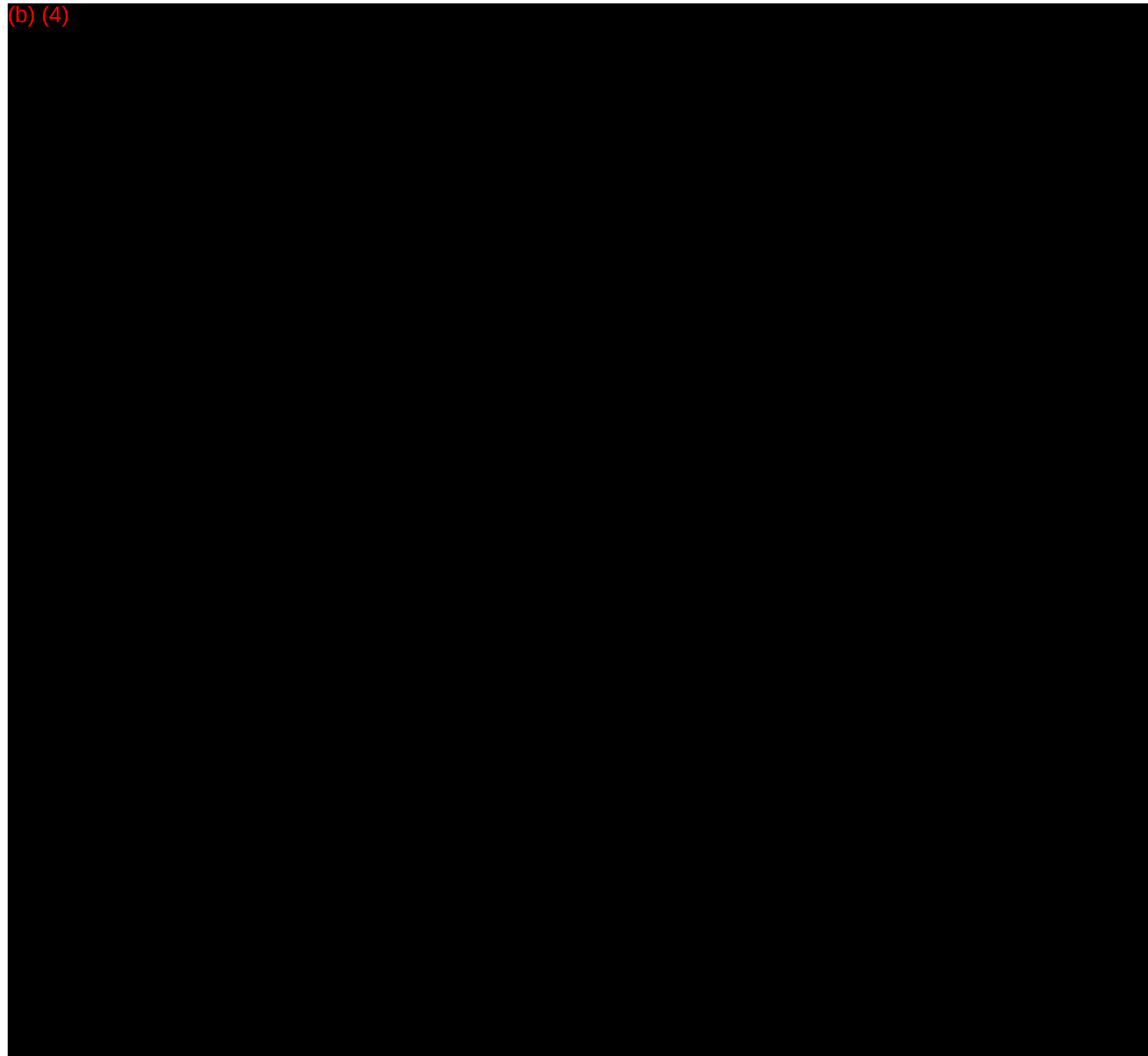
NOTE: The company claims, “the indications for use” are unaffected by the purposed changes in this PMA/S.

DEVICE DESCRIPTIONS

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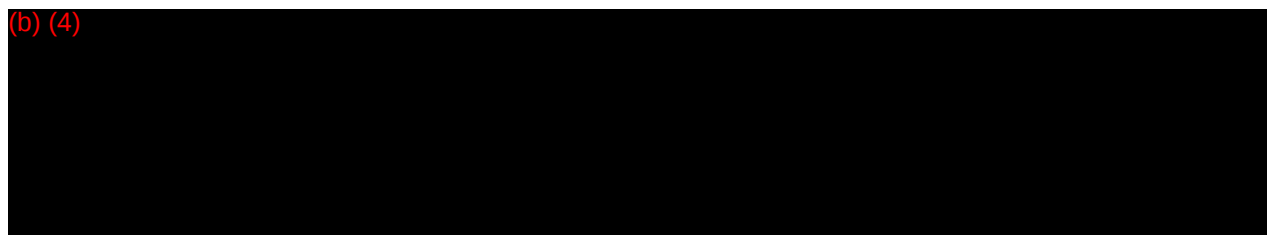
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THE SUMMARY FOR THE REVIEW

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BIOCOMPATIBILITY: N/A

ANIMAL STUDY: N/A

CLINICAL DATA: N/A

LABELING:

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CONCLUSION

Based on the information in the file, the company has provided the appropriate data to demonstrate the subject device is acceptable to be recommended for the approval, since this software tool will be used by the Medtronic field personnel only.