

St. Jude Medical Implantable Electronic Systems 15900 Valley View Court Sylmar, CA 91342 USA Main 818 362 6822 Fax 818 364 5814

May 25th, 2016

TUV SUD BABT FCB Octagon House, Segensworth Road, Fareham, Hampshire, PO15 5RL

Model Names and Differences

We, St. Jude Medical IESD, hereby request Family certification for the following RF electrically identical implantable pulse generators. The differences consist of battery capacities (either 5.3 or 7.5 Ah), type of therapy (Tonic or non-Tonic SCS/DBS or Dorsal Root Ganglion therapy (DRG), controlled by software) and method of connecting patient electrodes to the device (SJM,1.27 mm or DRG header).

Model 3660 Orion IPG, 5.3Ah, SCS, SJM header Model 3661 Orion IPG, 5.3Ah, SCS, 1.27mm header Model 3662 Orion IPG, 7.5Ah, SCS, SJM header Model 3663 Orion IPG, 7.5Ah, SCS, 1.27mm header Model 6660 Orion IPG, 5.3Ah, DBS, Tonic, SJM header Model 6661 Orion IPG, 5.3Ah, DBS, Tonic, 1.27mm header Model 6662 Orion IPG, 7.5Ah, DBS, Tonic, SJM header Model 6663 Orion IPG, 7.5Ah, DBS, Tonic, 1.27mm header Model 6663 Orion IPG, 7.5Ah, DBS, Tonic, SJM header Model 3665 Orion IPG, 5.3Ah, SCS, Tonic, SJM header Model 3665 Orion IPG, 7.5Ah, SCS, Tonic, SJM header Model 3667 Orion IPG, 7.5Ah, SCS, Tonic, SJM header Model 3664 Proclaim[™] 5 IPG, 5.3Ah, DRG, DRG header

Sincerely,

Name: Jorge Amely-Velez Title: Senior Principal Engineer St. Jude Medical IESD 15900 Valley View Court Sylmar, CA 91342