

St. Jude Medical Cardiac Rhythm Management Division (CRMD) 15900 Valley View Court Sylmar, CA 91342 USA Main 818 362 6822 Fax 818 364 5814

2019-10-15

TUV SUD America Inc. 10 Centennial Drive Peabody, MA 01960, USA

Dear Sir or Madam,

We, St. Jude Medical 15900 Valley View Court Sylmar, CA 91342, hereby certify the differences described below for all model families listed are valid and true.

Yours sincerely,

1/emph

Name: Perry Li Title: Staff Engineer, R&D

| Product Name  | Model Differences  |  |  |
|---------------|--|--|--|
|               | VR   | DR   | CRT-D (HF)   |
| Avant™        | CDVRA700Q  | CDDRA700Q  | CDHFA700Q  |
|               | <ul> <li>Tested Model (Baseline)</li> </ul>  | <ul> <li>Test Model (Baseline)</li> </ul>  | Tested Model (Baseline)  |
| Neutrino™ NxT | CDVRA800Q  | CDDRA800Q  | CDHFA800Q  |
|               | <ul> <li>No hardware or software<br/>difference from baseline.</li> </ul>              | <ul> <li>No hardware or software<br/>difference from baseline.</li> </ul>              | No hardware or software<br>difference from baseline.                                   |
|               | <ul> <li>Different product name and<br/>model number.</li> </ul>                       | <ul> <li>Different product name and<br/>model number.</li> </ul>                       | <ul> <li>Different product name and<br/>model number.</li> </ul>                       |
| Gallant™      | CDVRA500Q  | CDDRA500Q  | CDHFA500Q  |
|               | <ul> <li>No hardware or software<br/>difference from baseline.</li> </ul>              | <ul> <li>No hardware or software<br/>difference from baseline.</li> </ul>              | No hardware or software<br>difference from baseline.                                   |
|               | <ul> <li>Different product name and<br/>model number.</li> </ul>                       | <ul> <li>Different product name and<br/>model number.</li> </ul>                       | <ul> <li>Different product name and<br/>model number.</li> </ul>                       |
| Neutrino™ NxT | CDVRA600Q  | CDDRA600Q  | CDHFA600Q  |
|               | <ul> <li>No hardware or software<br/>difference from baseline.</li> </ul>              | <ul> <li>No hardware or software<br/>difference from baseline.</li> </ul>              | No hardware or software<br>difference from baseline.                                   |
|               | <ul> <li>Different product name and<br/>model number.</li> </ul>                       | <ul> <li>Different product name and<br/>model number.</li> </ul>                       | <ul> <li>Different product name and<br/>model number.</li> </ul>                       |
| Entrant™      | CDVRA300Q  | CDDRA300Q  | CDHFA300Q  |
|               | <ul> <li>Software change to<br/>accommodate different<br/>therapy settings.</li> </ul> | <ul> <li>Software change to<br/>accommodate different<br/>therapy settings.</li> </ul> | <ul> <li>Software change to<br/>accommodate different<br/>therapy settings.</li> </ul> |
|               | <ul> <li>No change to RF software.</li> </ul>  | <ul> <li>No change to RF software.</li> </ul>  | No change to RF software.  |
|               | <ul> <li>No hardware difference<br/>from baseline.</li> </ul>                          | <ul> <li>No hardware difference<br/>from baseline.</li> </ul>                          | <ul> <li>No hardware difference<br/>from baseline.</li> </ul>                          |
|               | <ul> <li>Different product name and<br/>model number.</li> </ul>                       | <ul> <li>Different product name and<br/>model number.</li> </ul>                       | <ul> <li>Different product name and<br/>model number.</li> </ul>                       |