

2024-07-25

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,

Name: Perry Li

Title: Associate Research Fellow

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Product Name	Bipolar DF4	Bipolar DF-1
	CDHFA700D	CDHFA700B
Avant™ HF	Tested Model (Baseline)	• Tested Model (Baseline)
Neutrino™ NxT HF	CDHFA800D	CDHFA800B
	No hardware or software	No hardware or software
	difference from baseline.	difference from baseline.
	Different product name	Different product name and
	and model number.	model number.
Gallant™ HF	CDHFA500D	CDHFA500B
	No hardware or software	No hardware or software
	difference from baseline.	difference from baseline.
	Different product name	Different product name and
	and model number.	model number.
Neutrino™ NxT HF	CDHFA600D	CDHFA600B
	No hardware or software	No hardware or software
	difference from baseline.	difference from baseline.
	Different product name	Different product name and
	and model number.	model number.
Entrant™ HF	CDHFA300D	CDHFA300B
	Software change to	Software change to
	accommodate different	accommodate different therapy
	therapy settings.	settings.
	• No change to RF software.	No change to RF software.
	No hardware difference	No hardware difference from
	from baseline.	baseline.
	Different product name	Different product name and
	and model number.	model number.