DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1350 Piccard Drive
Rockville, Maryland 20850

Ms. Brandy L. Corneil
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Medtronic Cardiac Rhythm Disease Management
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March 7, 2007

MDR report numbers:
(See Attachments 1 & 2)

Dear Ms. Corneil:

The Food and Drug Administration (FDA) received the above reports in accordance with the Medical Device Reporting (MDR) regulation. The reports are associated with your firm's Sprint Fidelis implantable defibrillation lead model 6949. To complete our evaluation, the following information is requested to address the postmarket performance of Sprint Fidelis defibrillation lead model numbers 6930, 6931, 6948, 6949:

1. To assist us in determining the overall failure rate for the Sprint Fidelis defibrillator lead since first marketed in the U.S., please provide an Actuarial Survival Probability table for each Sprint Fidelis model your firm has marketed (models 6930, 6931, 6948, and 6949).

2. For each model number, please submit the number of Sprint Fidelis defibrillation leads manufactured, distributed, implanted and explanted in the U.S.

3. Submit any device failures confirmed by manufacturer failure analyses that have not been provided to FDA under the MDR reporting regulation (See Attachment 2).

4. Please describe any internal and/or regulatory action(s) taken in response to MDRs (internal actions such as manufacturing, labeling, training, design and/or quality assurance, and regulatory actions such as PMA supplement, 30 day notice, CAPA and recalls):

   a) In reference to Attachment 1 (see items c, e through o, and q through t), there are reports for a total of 197 Sprint Fidelis model 6949 defibrillator leads prematurely explanted and confirmed with a fracture. One MDR for model 6949 (MDR 2949622-2005-00461) involves a death during the implant procedure, with the MDR "manufacturer evaluation result code" reported as number "708" (708 = device performed according to specifications) and the lead analysis revealed "distal conductor and coil was distorted and fractured in a manner consistent with overstress (implant damage)". For all confirmed lead fractures, breakages and distortions, please describe any action(s) taken to address the occurrence of all confirmed fractures observed with this device model 6949.

   b) For manufacturer confirmed lead fractures associated with the Sprint Fidelis ICD lead models 6930, 6931 and 6948.

   c) One model 6949 lead was mislabeled (See Attachment 1, item a: MDR 2649622-2005-00529).

Please send your response within 30 days from the date of this letter to the address above. You may fax your response to my attention at 240-276-3301 and email to diane.dwyer@fda.hhs.gov. Please cc your email response to megan.moynahan@fda.hhs.gov and nicole.wolanski@fda.hhs.gov. In responding, please reference the MDR report numbers and this letter. If you have any questions, please call me at 240-276-3423.

Sincerely yours,

Diane Dwyer
Nurse Consultant
Product Evaluation Branch 1
Division of Postmarket Surveillance
Office of Surveillance and Biometrics
Center for Devices and Radiological Health

Attachment 1 (Seven pages: MDRs: Sprint Fidelis Model 6949 ICD leads)
Attachment 2 (One page: 18 MDRs need failure analysis results for model 6949)

Attachment 1 – MDR report numbers:
Medtronic Sprint Fidelis Model 6949 ICD leads

a) Labeling problem noted: (n=1)
2649622-2005-00529 (US) both HV pins (HVB & HVX) labeled as HVB.

b) Patient problem noted post-implant, premature explant required: (n=3)
Diaphragmatic stimulation with high pain threshold. Lead received with MCRD (steroid) ring missing. Same event, 2 reports: 2649622-2005-00850 & (b)(6) (b)(6) (US) 6 weeks

Shock while running to bus:
Lead had 2 setscrew marks on connector pin. One centered on pin but other is too proximal on pin to assure continuous electrical contact.
2649622-2005-01029(US) implanted 6 weeks

c) Device problem noted during or same day of implant procedure: (n=3)
Defib conductor fractured due to overstress: 2649622-2005-00375 (US)

Proximal conductor fractured under the distal end of the RV defib coil:
2649622-2006-00220 (US) appears cable damaged by a cutter during manufacturing.
Sensing problems at implant.

Proximal conductor fractured:
2649622-2006-00798 & (b)(6) (b)(6) (US) explanted 1 day after implant

d) Device problem noted post-implant, premature explant required :(n=2)
Proximal conductor weld defective (US) implanted one week
2649622-2005-00912 (US) implanted 11 days
2649622-2005-00934 (US) implanted 2 days

e) SVC conductor and filars are fractured at the distal end of the proximal cross groove: (n=1)
2649622-2007-00147 (US) implanted 15 months

f) Proximal conductor fractured under the distal end of the RV defib coil: (n=4)
2649622-2006-00249 (US) implanted 8.5 months
2649622-2006-00641 (US) implanted 13 months
2649622-2006-00946 (US) implanted 6.5 months
2649622-2007-00132 (US) implanted 2 years

g) Proximal conductor is fractured under the right ventricular coil: (n=4)
2649622-2007-00053 (US) implanted 13 months
2649622-2007-00054 (US) implanted 16 months
2649622-2007-00148 (US) implanted 14 months
2649622-2007-00149 (US) implanted 2 years

h) Right ventricular (RV) conductor is fractured at the proximal end of the RV coil: (n=1)
2649622-2006-01462 (US) implanted 8 months

i) RV conductor is fractured in the RV connector leg and stretched and broken the conductor coating. Tensile fracture most likely related to implant damage: (n=1)
2649622-2007-00136 (US) implanted 13 months

Attachment 1 – page 2 - MDR report numbers:
Medtronic Sprint Fidelis Model 6949 ICD leads

j) Proximal conductor and the RV conductor are fractured under the distal end of the RV coil: (n=1)
2649622-2006-01328 (US) implanted 19 months

k) Proximal cable and the right ventricle (RV) cable were fractured under the RV coil: (n=1) 2649622-2006-01067 (US) implanted 16 months

l) Proximal conductor fractured and or adjacent to the weld in the trifurcation: (n=1)
2649622-2006-00501 & (b)(6) (b)(6) (US) implanted 2 weeks Patient to ER for multiple shocks.

m) Proximal conductor fracture: (n=63)
2649622-2005-00086(US) implanted 4 days
2649622-2005-00842 (US) implanted 11 months
2649622-2005-00916 & (b)(6) (b)(6) (US) implanted 9 months
2649622-2005-00932 (US) 10 months
2649622-2005-00948(US) implanted 9 months
2649622-2006-00209 (US) implanted 13 months
2649622-2006-00321 (US) implanted 9 months
2649622-2006-00368 (US) implanted 7.5 months
2649622-2006-00369 (US) implanted 6 weeks
2649622-2006-00524 & (b)(6) (b)(6) (US) implanted 2 months
2649622-2006-00616 (US) implant duration unknown
2649622-2006-00630 (US) implanted 13 months
2649622-2006-00662 (US) implanted 15 months
2649622-2006-00725 (US) implanted 8 months
2649622-2006-00773 (US) implanted 8 months
2649622-2006-00791 & (b)(6) (b)(6) (US) implanted 6.5 months
2649622-2006-00524 & (US) implanted 2 months
2649622-2006-00791 & (US) implanted 7.5 months
2649622-2006-00834 (US) implanted 15 months
2649622-2006-01110 (US) implanted 19 months
2649622-2006-01116 (US) implanted 9 months
2649622-2006-01124 (US) implanted 15 months
2649622-2006-01149 (US) implanted 15 months
2649622-2006-01157 (US) implanted 9 months
2649622-2006-01172 (US) implanted 14 months
2649622-2006-01249 (US) implanted 16 months
2649622-2006-01298 (US) implanted 18 months
2649622-2006-01299 (US) implanted 17 months
2649622-2006-01062 (US) implanted 19 months
2649622-2006-01391 (US) implanted 11 months
2649622-2006-01447 (US) implanted 11 months
2649622-2006-01560 (US) implant duration unknown
2649622-2006-01567 (US) implanted 4 months
2649622-2006-01593 (US) implanted 18 months
2649622-2006-01635 (US) implanted 22 months

Attachment 1 – page 3 - MDR report numbers:
Medtronic Sprint Fidelis Model 6949 ICD leads

2649622-2006-01637 (US) implanted 14 months
2649622-2006-01648 (Germany) implanted 19 months
2649622-2006-01650 (US) implanted 3 months
2649622-2006-01687 (US) implanted 22 months
2649622-2006-01701 (US) implanted 10 months
2649622-2006-01702 (US) implanted 10 months
2649622-2006-01712 (US) implanted 19 months
2649622-2007-00029 (US) implant duration unknown
2649622-2007-00031 (US) implanted 22 months
2649622-2007-00039 (US) implanted 19 months
2649622-2007-00063 (US) implanted 21 months
2649622-2007-00072 (US) implanted 7 weeks
2649622-2007-00075 (US) implanted 17 months
2649622-2007-00082 (US) implanted 4 months
2649622-2007-00133 (US) implanted 9 months
2649622-2007-00152 (US) implanted 21 months
2649622-2007-00157 (US) implanted 14 months
2649622-2007-00166 (US) implanted 21 months
2649622-2007-00169 (US) implanted 18 months
2649622-2007-00204(US) implanted almost one year
2649622-2007-00218 (US) implanted 23 months
2649622-2007-00242 (US) implanted 23 months
2649622-2007-00298 (US) implanted 15 months
2649622-2007-00315 (US) implanted 20 months
2649622-2007-00340 (US) implanted 20 months
2649622-2007-00342 (US) implanted 2 years
2649622-2007-00345 (US) implanted 21 months
2649622-2007-000351 (SZ) implanted 18 months

n) Distal conductor fracture: (n=55)
2649622-2006-00004(US) implanted 13 months
2649622-2006-00212 (US) implanted 8 months
2649622-2006-00354 (US) implanted 11 months
2649622-2006-00371 (US) implanted 6 months (insulation anomalies cut or melted)
2649622-2006-00527 (US) implanted 1 year
2649622-2006-00723 (US) implanted 14 months (also found intermittency between the connector pin and cap.
2649622-2006-00755 (US) implanted 10 months
2649622-2006-00757 (US) implanted 7.75 months
2649622-2006-00807(US) implanted 6 months
2649622-2006-00919 (US) implanted 17 months
2649622-2006-00936 (US) implanted 9 months
2649622-2006-00937 (US) implanted 11 months
2649622-2006-00950 (US) implanted 7 months
2649622-2006-00968 (US) implanted 17 months
2649622-2006-01117 (US) implanted 14 months

Attachment 1 – page 4 - MDR report numbers:
Medtronic Sprint Fidelis Model 6949 ICD leads

2649622-2006-01121 (US) implanted 9 months
2649622-2006-01195 (US) implanted 19 months
2649622-2006-01196 (US) implanted 3 days
2649622-2006-01224 (US) implanted 16 months
2649622-2006-01227 (US) implanted 13 months
2649622-2006-01228 (US) implanted 19 months
2649622-2006-01227 (US) implanted 13 months
2649622-2006-01277 (NICE, FS) implanted 8 months
2649622-2006-01287 (US) implanted 8 months
2649622-2006-01303 (Germany) implanted 17 months
2649622-2006-01066 (US) implanted 13 months
2649622-2006-01068 (US) implanted 16 months
2649622-2006-01069 (US) implanted one year
2649622-2006-01070 (US) implanted 9 months
2649622-2006-01071 (US) implanted 19 months
2649622-2006-01381 & (b)(6) (b)(6) (US) implanted 10 months
2649622-2006-01450 (unknown country) implanted 10 months
2649622-2006-01451 (US) unknown implant duration
2649622-2006-01486 (US) implanted 4 months
2649622-2006-01491 (US) implanted 14 months
2649622-2006-01501 (US) implanted 24 months
2649622-2006-01592 (US) implanted 21 months
2649622-2006-01626 (US) implanted 19 months
2649622-2006-01662 (US) implanted one year
2649622-2006-01663 (US) implanted 18 months
2649622-2006-01699 (US) implanted 18 months
2649622-2006-01707 (US) implanted 23 months
2649622-2007-00010 (US) implanted 15 months
2649622-2007-00036 (US) implanted 14 months
2649622-2007-00048 (US) implanted 18 months
2649622-2007-00071 (US) implanted 13 months
2649622-2007-00137 (US) implanted 11 months
2649622-2007-00203 (US) implanted 7 months
22649622-2007-00044 (US) implanted almost one year
2649622-2007-00211 (US) implanted 6 months
2649622-2007-00214 (GR) implanted 19 months
2649622-2007-00228 (US) implanted 11 months
2649622-2007-00241 (AU) implanted11 months
2649622-2007-00318 (US) implanted 23 months
2649622-2007-00352 (UK) unknown implant duration

o) Distal conductor fracture (overstress): (n=24)
2649622-2005-00392 (SZ) implanted 3 months
2649622-2005-00506 (US) implanted 19 days
2649622-2005-00642 (US) implanted 7 months
2649622-2005-00843 & (b)(6) (b)(6) (US) implanted 10 months
2649622-2005-00915(US) implanted 6 weeks
2649622-2005-00941(Prague) implanted 6 months
2649622-2006-00179 (Hamburg) zip 21075 implanted 6 days

Attachment 1 – page 5 - MDR report numbers:
Medtronic Sprint Fidelis Model 6949 ICD leads

2649622-2006-00431 (US) implanted 13 months
2649622-2006-00440 (US) implanted 13 months
2649622-2006-00442 (US) implanted 9 months
2649622-2006-00687 (US) implanted 2 weeks (burn mark on coil noted).
2649622-2006-00709 (US) implanted 9 months
2649622-2006-00713 (University of Mainz in Mainz) implanted 11 months
2649622-2006-00731 (US) implanted 7 months distal coil fractured and distorted In the connector and helix is retracted most likely during repositioning attempt.
2649622-2006-00891 (US) implanted 15 months
2649622-2006-00942 (US) implanted 1 year (RV cable is fractured in the connector leg at the distal end of the strain relief coil).
2649622-2006-00984 (Canada) implanted 8 months
2649622-2006-01166 (US) implanted 19 months
2649622-2006-01381 & (b)(6) (b)(6) (US) implanted 10 months
2649622-2006-01390 & (b)(6) (b)(6) (US) implanted 11 months
2649622-2006-01490 (US) implanted 9 days
2649622-2006-01530 (US) implanted 10 months
2649622-2006-01546 (US) implanted 14 months
2649622-2007-00297 (US) implanted 7 months

p) Distal conductor damaged in connector and helix fully retracted: (n=1)
2649622-2005-01005(US) implanted one month

q) Defib conductor fracture (overstress): (n=8)
2649622-2005-00671(US) implanted 5 months
2649622-2005-00805 (US) implanted 4 months
2649622-2005-00925 (US) implanted 8.5 months
2649622-2006-00570 (US) implanted 6 months
2649622-2006-00809 & (b)(6) (b)(6) (US) implanted 1 month
2649622-2006-01146 (US) implanted 3 months
2649622-2006-01168 (US) implanted 3 days
2649622-2006-01456 (US) implanted one day

r) Defib conductor fracture: (n=28)
2649622-2005-00862 (unknown) implanted 6 months
2649622-2005-00864 & (b)(6) (b)(6) (US) implanted 6 months
2649622-2005-00945(US) implanted 7.5 months
2649622-2005-00952(US) implanted 6 months
2649622-2005-00864 & (b)(6) (b)(6) (US) implanted 10 months
2649622-2006-00111 (US) implanted 8 months
2649622-2006-00201 (US) implanted 6 months
2649622-2006-00209 (US) implanted 13 months
2649622-2006-00493 & (b)(6) (b)(6) (US) implanted 6 months
2649622-2006-00568 (US) implanted 11 months

Attachment 1 – page 6 - MDR report numbers:
Medtronic Sprint Fidelis Model 6949 ICD leads

2649622-2006-00598 (US) implanted 17 months
2649622-2006-00631 (US) implanted 11 months
2649622-2006-00809 & (b)(6) (b)(6) (US) implanted 1 month
2649622-2006-00833 (US) implanted 10 months
2649622-2006-00845 (US) implanted 3 months. Fracture in high voltage circuit of the lead.
2649622-2006-01008 (Germany) implanted 17 months
2649622-2006-01290 (US) implanted 5.5 months
2649622-2006-01390 & (b)(6) (b)(6) (US) implanted 13 months
2649622-2006-01455 (US) implanted 8 months
2649622-2006-01466 (US) implanted 2 months
2649622-2006-01469 (US) implanted 18 months
2649622-2006-01519 (US) implanted 5 months
2649622-2006-01639 (unknown foreign) implanted 11 months
2649622-2007-00055 (US) implanted 14 months (outer insulation breached)
2649622-2007-00130 (US) implanted 18 months
2649622-2007-00135 (US) implanted 3.5 months
2649622-2007-00212 (US) implanted 5 months
2649622-2007-00336 (US) implanted 19 months

s) Several conductors fractured: (n=1)
2649622-2006-01475 (US) implanted 19 months

t) Several conductors fractured, appears due to subclavian crush: (n=1)
2649622-2006-00318 (US) implanted 9 months

u) Distal conductor damaged in connector and helix fully retracted :(n=1)
2649622-2005-01005(US) implanted one month

v) Blood present entire length of lead in distal conductor as well as in medial and electrode end of right ventricular conductor lumen. 2 cuts noted in distal and RVconductor lumens: (n=1)
2649622-2006-00608 (US) implanted 5 weeks

w) Distal conductor distorted :(n=1)
2649622-2006-00870 (US) implanted 7 days (also had high threshold)

x) Intermittent contact between connector pin and pin cap: (n=1)
2649622-2007-00111 (Italy) implant duration unknown

y) Helix: bent or distorted (n=3)
Helix bent: n=1)2649622-2005-00440 (US) implanted 3 weeks
Helix distorted: (n=2) 2649622-2005-00670 (US) implanted 2 months
2649622-2006-00894 (US) implanted 2 months (helix/lobe distorted/bent)

z) Outer tubing overlay issue: (n=11)

Breached cut: (n=6)

Attachment 2 – Please submit failure analysis results for the following 18 MDR report numbers: <u>Medtronic Sprint Fidelis Model 6949 ICD leads</u>

a) **Voluntary MedWatch (report number, serial number, country, implant time):**
MW1040340 (serial number (b) (6) (US) implant duration unknown.
MW1037213 (serial number (US) implanted one year
MW1041870 (serial (b) (6) (US) implanted one year
MW1040889 (serial (b) (6) (US) implanted 22 months.
MW1041871 (serial (b) (6) (US) implanted 22 months.
MW1041872 (serial (b) (6) (US) implanted 16 months.
MW1041873 (serial (US) implanted 23 months
MW1041874 (serial (US) implanted 13 months
MW1041885 (serial (US) implanted 18 months

b) **User facility (report number, serial number, country, implant time)**
(b) (6) (serial (b) (6) (US) implant duration unknown.
(serial (US) implanted 19 months

c) **Manufacturer (MDR number, country, implant time)**
2649622-2006-00806 (US) implanted 8 months
2649622-2006-00987 (US) implanted 14 months
2649622-2006-01582 (serial (b) (6)) (foreign city: Haau) implanted 2 months
2649622-2006-01587 (b) (6) (SP) implanted 3.5 months
2649622-2006-01624 (US) implanted 19 months
2649622-2006-01717 (US) implanted one month
2649622-2006-01718 (US) implanted 21 months

Medtronic Sprint Fidelis Model 6949 ICD leads

2649622-2006-00031(US) implanted 5 days
2649622-2006-01288 (US) implanted 5 months
2649622-2006-01063 (US) implanted 1 day appears due to suturing of anchoring sleeve.
2649622-2007-00134 (US) implanted 25 days
2649622-2005-01024(US) implanted 5 months (All insulators breached cut)
2649622-2006-00090(Bochum) implanted 6 days (outer insulation breached cut)

Possible implant damage: (n=1)

2649622-2005-00970(US) implanted 3 days

Appears melted from cautery: (n=2)

2649622-2005-00977(US) implanted 2 months
2649622-2006-00898 (US) implanted 11 weeks

Outer tubing esc breach: (n=1)

2649622-2006-00905 (US) implanted 5 months (diaphragmatic stimulation, blood ingress noted at repositioning)

Outer insulation breached (clavicle-rib crush): (n=1)

2649622-2006-00947 (US) implanted 11 months