Health Canada Santé Canada

Mandatory Medical Device Problem Reporting Form for Industry

CANADA VIGILANCE - MEDICAL DEVICE PROBLEM REPORTING PROGRAM

If more space is required, please attach additional sheets
Fields required to be completed for updates/final reports are indicated by an *

A. REPORTER INFORMATION

1. i. Reporter Type

☐ Manufacturer ☑ Importer

In the case where the reporter is the importer:

ii. Did the importer report the incident to the manufacturer?

☑ Yes ☐ No

iii. Is the importer also submitting the report on behalf of the manufacturer?

☑ Yes ☐ No

2. Reporter Contact Information *

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F: cda0d358e1efab57e4dff942d40471a3

3. Reporter File No. *

MDPR-2020-00346-01

4. Health Canada File No. (if applicable) *

5. Type of Report *

☐ Preliminary ☐ Update ☑ Final ☐ Preliminary & Final

If "preliminary" only, anticipated date for the final report:

(YYYY-MM-DD)

If "update/final", date the previous report was submitted to Health Canada:

2020-08-17 (YYYY-MM-DD)

6. Date Submitted *

2020-09-23 (YYYY-MM-DD)

		Importer
7. Name and Address	St. Jude Medical, CRMD 15900 Valley View Court Sylmar, CA 91342	Abbott Medical Canada, Co. 6975 Creditview Rd Unit #1 Mississauga, ON, Canada L5N 8E9
8. Health Canada assigned company identification number (if known):	107942	107941
9. Establishment License Number (if applicable):		19

B. INCIDENT INFORMATION

1. Classification of Incident *

i. ☑ 10-Day ☐ 30-Day

ii. ☑ Canadian ☐ Foreign

iii. ☑ Investigational testing ☐ Special Access Program

☐ Radiation emitting device (if applicable)

2. Date of Incident

2020-08-07

3. Reporter's Awareness Date

2020-08-09

4. Patient Consequences

T
p

44ead057b2ecd9e3965d764d33ec143e

5. Details of Incident

ddfeb6d27f1c0f78b916a385a0637ec2

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
Nanostim Leadless Cardiac Pacemaker

2. Control/Lot/Serial No.
7494

3. Expiration Date
2016-06-30 (YYYY-MM-DD)

4. i. Device Classification
☐ I ☐ II ☐ III ☑ IV

ii. Device License No.
ITA 223064

iii. Device Identification No
N/A

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
S1DLCP

5. Software Version
N/A

6. Age of Device
2016-01-18

7. How long was the device in use?
1520 days

8. Was the device labelled as sterile?
☑ Yes ☐ No

9. Availability of device for evaluation
☐ Destroyed ☐ Returned to Manufacturer/Importer
☑ Neither (with explanation)

The device was unable to be retrieved so was left implanted in the patient.

D. COMPLAINANT INFORMATION

1. Complainant is a:
☐ Consumer ☑ Health Professional ☐ Other

2. Name of Complainant
D086b85befc959c6cedafc3b6544eddd7

3. Name of Health Care Facility (if applicable)
Ffa6b301bbd113780248dead6f542c206

4.
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C
Ta3397d6178c55ffb704d5351d3cec567

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cc7f928692a932ac6cc7fec954714856

personal information collected under this program, visit the Personal Information Bank; Health Canada; Health Products and Food Branch; Branch Incident Reporting System; HC PPU 088 at:

http://infosource.gc.ca/inst/1476/1476-fedemp00- eng.asp

E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline

087b478c02f47c2ea2b6eac8c2060cd5

This section only applies for preliminary & final, and final reports

2. Root Cause of Problem

e5fb64baab56857f4a8e0b5d800ca32d

3. Corrective Actions taken as a result of the investigation

a6ab9b627afcd0a371190d615d2f14f3