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 *

e28ac36b93eb68254847e2372505d022

3. Reporter File No. *

0703493418

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:

2020-01-16 (YYYY-MM-DD)

6. Date Submitted *

2020-09-29 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	MEDTRONIC INC. 710 MEDTRONIC PARKWAY NE, MINNEAPOLIS, MN, US Postcode:55432 Tel:(+1-763)5144000 Fax:(+1-763)5144879	MEDTRONIC CANADA ULC 99 HEREFORD STREET, BRAMPTON, ON, CANADA Postcode:L6Y 0R3 Tel:(800)268-5346 Fax:(905) 460-3992
8. Health Canada assigned company identification number (if	114663	106916
9. Establishment License Number (if applicable):	NA	35

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

2019-11-28

3. Reporter's Awareness Date

2019-11-29

4. Patient Consequences

9a2781d46108e3d2c4679e09dc83ce94

5. Details of Incident

I

6a21ccf9d4801cf3659b396b9c2f0139

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *

Evera MRI XT DR SureScan

2. Control/Lot/Serial No.

PGZ634702S

3. Expiration Date

2020-07-28

4. i. Device Classification

☐ I ☐ II ☐ III ☒ IV

ii. Device License No.

92108

iii. Device Identification No

1c3421f3a5aef6e8243012301cf65985

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

DDMB2D4

5. Software Version

Not Applicable

6. Age of Device

Manufacture Date: 2019-01-28

7. How long was the device in use?

Implant Date: 2019-11-28

8. Was the device labelled as sterile?

☒ Yes ☐ No

9. Availability of device for evaluation

☐ Destroyed ☐ Returned to Manufacturer/Importer

☒ Neither (with explanation)

Still in Use

D. COMPLAINANT INFORMATION

1. Complainant is a:

☐ Consumer ☒ Health professional ☐ Other

2. Name of Complainant

04a34afd619c990e0a587e2e2377287f

3. Name of Health Care Facility (if applicable)

eac50635aef0efa01522058e64aae9e1

4. Address

eac50635aef0efa01522058e64aae9e1

5. Telephone No. and/or E-mail Address

eac50635aef0efa01522058e64aae9e1

of the complainant and/or reporter will be protected as personal information under the *Privacy Act*, under the *Access to Information Act* in the case of an access to information request. For details with regard to 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

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

2. Root Cause of Problem

d8fbab5796d20c3386e34cb9974c2710

3. Corrective Actions taken as a result of the investigation

b89664c643a4879e24fff2f0c3af0395