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 *

567d83f2dce5750d21c7d98d26bb67a1

3. Reporter File No. *

0703158253

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:

2019-06-11 (YYYY-MM-DD)

6. Date Submitted *

2019-08-20 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	HEARTWARE INC 14400 NW 60TH AVENUE,MIAMI LAKES, FL, US Postcode:33014 Tel:+1(763)526-2723 Fax:XXX	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	131863	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

2019-05-16

3. Reporter's Awareness Date

2019-05-16

4. Patient Consequences

ea04e9e2d008268b715a0c23cdfd7c8f

5. Details of Incident

I

a1500f0c1b6f33d9aeb90f7df154e76c

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *

HEARTWARE VENTRICULAR ASSIST SYSTEM

2. Control/Lot/Serial No.

HW31136

3. Expiration Date

2019-11-30

4. i. Device Classification

☐ I ☐ II ☐ III ☒ IV

ii. Device License No.

94844

iii. Device Identification No

585940

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

1104

5. Software Version

Not Applicable

6. Age of Device

Implant Date:2018-10-03

7. How long was the device in use?

UNKNOWN

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

bc2aa79a2076b784e8915bd83bdf994e

3. Name of Health Care Facility (if applicable)

58a10140a1735a5cbfb59ffc15038309

4. Address

f51e553a42e1db469bdeda6027651b90

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

653ba16297f41af13e9d667fd91d98c2

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

589d01c1bb259207f83ae93c555eae33

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

2. Root Cause of Problem

1e8c754885294a5d074cc5f418a8a6d5

3. Corrective Actions taken as a result of the investigation

a374688aa91834d9673f5294c0b04dd1