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 *

7f49730bf88bd032be2e3539e3ef3c5f

3. Reporter File No. *

1081718

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:

2019-12-13 (YYYY-MM-DD)

6. Date Submitted *

2020-04-27 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	Joerns Healthcare 2100 Design Road Arlington, TX 76014	Joerns Healthcare Canada 35 Consortium Court London, ON N6E 2S8
8. Health Canada assigned company identification number (if known):	133968	125199
9. Establishment License Number (if applicable):		

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

2019-10-31 (YYYY-MM-DD)

3. Reporter's Awareness Date

2019-11-14 (YYYY-MM-DD)

4. Patient Consequences

0914349e68550ded75519920f65dd9d3

5. Details of Incident

05efdf00357f80a2754583a3ad9dfc42

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
Hoyer Advance-E

2. Control/Lot/Serial No.
1510L0848

3. Expiration Date
(YYYY-MM-DD)

4. i. Device Classification
(•) I ( ) II ( ) III ( ) IV

ii. Device License No.

iii. Device Identification No

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
HOY-ADVANCE-E

5. Software Version

6. Age of Device
4 years

7. How long was the device in use?
3+ years

8. Was the device labelled as sterile?
( ) Yes (•) No

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

In patients' possession.

D. COMPLAINANT INFORMATION

1. Complainant is a:
( ) Consumer ( ) Health professional (•) Other

2. Name of Complainant
b8197a8b0706a93bda8589dd4c9f90ca

3. Name of Health Care Facility (if applicable)
d41d8cd98f00b204e9800998ecf8427e

4. Address
47ebe66052864b08f75aee9ae15a96a8

5. Telephone No. and/or E-mail Address
18c4ae803632949b05744c8716994175

Privacy Notice Statement: For the purposes of the Canada Vigilance -Medical Device Problem Reporting Program, information related to the identity of the complainant and/or reporter will be protected as personal information under the *Privacy Act*, and 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: https://www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/access-information-privacy/info-source-federal-government-employee-information.html#a25

E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline

ea3c7cb291bd944efaed7fa4dd0e98b9

2. Root Cause of Problem

d8779ff1a935b6b78f5e6fe2944d1d9c

3. Corrective Actions taken as a result of the investigation

d8779ff1a935b6b78f5e6fe2944d1d9c