

**ONTARIO
SUPERIOR COURT OF JUSTICE**

BETWEEN:

SHIRLEY HOULE AND ROLAND HOULE

Plaintiffs

- and -

ST. JUDE MEDICAL INC., and ST. JUDE MEDICAL CANADA, INC.

Defendants

Proceeding under the *Class Proceedings Act, 1992*

NOTICE OF MOTION

(Certification Motion returnable October 15, 2018)

THE PLAINTIFFS will make a motion to the Honourable Mr. Justice Perell on October 15 - 17, 2018 at 10:00 a.m. or as soon after that time as the motion can be heard, at Osgoode Hall Court House, 130 Queen Street West, Toronto, Ontario.

PROPOSED METHOD OF HEARING:

The motion is to be heard orally.

THE MOTION IS FOR:

- (a) An order:
- a. certifying this action as a class proceeding pursuant to the *Class Proceedings Act, 1992*, SO 1992, c 6, as amended (the *CPA*).
 - b. defining the classes as:
 - (i) The “Patient Class” consisting of every person resident in Canada that has been implanted with one of the following of models St. Jude Defibrillator, manufactured between January 2010 and May 23, 2015:
 - (1) Fortify;
 - (2) Fortify Assura;
 - (3) Forify Assura MP;
 - (4) Unify;
 - (5) Unify Assura; and
 - (6) Unify Quadra (together, the “Defibrillators”)
 - (ii) The “Family Class” consisting of all dependants of members of the Patient Class, as defined by section 61 of the *Family Law Act* R.S.O. 1990 c.F.3 s.61 and similar legislation in other Provinces, as listed in Schedule “A”, where applicable.
 - c. Certifying the following common issues:

Common Facts

1. Are the Defibrillators subject to premature and rapid battery depletion?
2. If so, what is the cause of the premature and rapid battery depletion?

Negligence

3. Did the Defendants owe a duty of care to the Class Members with respect to the:

- a. design;
- b. development;
- c. pre-market and after-market testing;
- d. manufacturing;
- e. distribution;
- f. marketing;
- g. sale;
- h. regulatory compliance;
- i. representations to medical practitioners; and
- j. recall

of the Defibrillators?

4. Did the Defendants owe the Class Members a duty of care to ensure that the batteries in the Defibrillators were not subject to rapid and premature depletion?

5. If the answer to 3 or 4 is yes, what was the appropriate standard of care owed by the Defendants, or either of them, to the Class?

6. If a duty of care was owed to the Class by the Defendants, or either of them, did the Defendants, or either of them, breach such a duty of care?

If so, what was the nature of the breach?

7. If the Defibrillators are subject to premature and rapid battery depletion, did the actions of the Defendants, or either of them, cause or contribute to this problem?

8. If the Defibrillators are subject to premature and rapid battery depletion, are they defective and/or unfit for their intended use?

Duty to Warn

9. If the Defibrillators are subject to premature and rapid battery depletion, when did the Defendants first learn of this fact?
10. Did the Defendants, or either of them, owe a duty to the Class to conduct post-market monitoring and surveillance of the functionality of the Defibrillators?
11. If so, did the Defendants, or either of them, owe a duty to the Class to warn of the potential premature and rapid battery depletion problem? If so, when did such a duty arise?
12. If a duty to warn of the potential premature and rapid battery depletion problem was owed to the Class, did the Defendants, or either of them, fail to warn the Class on a timely basis?

Damages and Punitive Damages

13. Can the damages of the Class Members be determined, in whole or in part, on an aggregate basis? If so, who should pay what amount and to whom?
14. Does the Defendants' conduct, or the conduct of either one of them, warrant an award of punitive damages, and if so in what amount, and how should the punitive damages be allocated to the Class?

Administration

15. Should the Defendants, or either of them, pay the costs of administering and distributing any recovery to all or part of the Class?

Interest

16. Should the Defendants, or either of them, be ordered to pay pre-judgment interest to all or part of the Class?
17. If so, how should the pre-judgment interest be calculated?

- d. appointing Shirley Houle as the Representative Plaintiff on behalf of the Patient Class;
- e. appointing Roland Houle as the Representative Plaintiff on behalf of the Family Class;
- f. declaring that the causes of action asserted are negligence and breach of duty to warn, and derivative actions under Section 61 of the *Family Law Act*, R.S.O. 1990, c F.3 and similar legislation in other provinces and territories;
- g. approving the Plaintiff's litigation plan;
- h. requiring the Defendants to pay the costs of providing notice of certification of the action as a class proceeding to the Class, and approving a form of notice of certification;
- i. requiring the Defendants to disclose to the Plaintiffs the names, contact information, implanted Defibrillator model and serial number, and implantation date for each member of the Patient Class;
- j. staying any other proceeding based on the facts giving rise to this proposed class proceeding;
- k. declaring that no other proceeding based upon the facts giving rise to this proceeding may be commenced without leave of the court;
- l. that the Defendants shall pay to the Plaintiffs their costs of this motion, fixed and payable forthwith; and
- m. Such further and other relief as this Honourable Court deems just.

THE GROUNDS FOR THE MOTION ARE:

- (a) This action was commenced on March 30, 2017 pursuant to the *CPA*;

- (b) The Plaintiffs assert that the Defendants were negligent in the research, development, pre-market testing, manufacturing, representations to regulators, post-market monitoring and surveillance, warning and recall of the Defibrillators as the Defibrillators were manufactured by the Defendants containing a lithium battery that was prone to forming lithium clusters that could cause a short circuit between the battery terminals resulting in an unpredictable and rapid draining of battery power;
- (c) The Defendants knew, or ought reasonably to have known, that the Defibrillators' batteries were susceptible to rapid battery depletion, with little or no warning, leaving the Patient Class vulnerable to injury and death;
- (d) The Defendants failed in their duty to warn the Class that the Defibrillators' batteries were susceptible to rapid battery depletion, although the fact was known, or reasonably ought to have been known from at least 2011. As a result, the Patient Class was left vulnerable to injury and death as a result of the Defibrillators failing to perform their life-saving function;
- (e) The Defendants, after they knew, or ought reasonably to have known, of the risks associated with the Defibrillators, continued actively to encourage implantation of the Defibrillators, and continued to introduce them into the stream of commerce, including after they issued the recall of the Defibrillators;
- (f) The proposed representative plaintiff, Shirley Houle, seeks to advance claims against the Defendants on her own behalf and on behalf of others similarly situated as the Patient Class;

- (g) The proposed representative plaintiff, Roland Houle, seeks to advance claims under Section 61 of the *Family Law Act*, RSO 1990, c F.3 against the Defendants on his own behalf and on behalf of others similarly situated as the Family Class;
- (h) The pleadings disclose causes of action against the Defendants in negligence and breach of the duty to warn, together with causes of action under Section 61 of the *Family Law Act*, R.S.O. 1990, c F.3 and similar legislation in other provinces and territories;
- (i) There is a class consisting of every person resident in Canada that has been implanted with one of the following of models St. Jude Defibrillator, manufactured between January 2010 and May 23, 2015: Fortify, Fortify Assura, Forify Assura MP, Unify, Unify Assura; and Unify Quadra (the Patient Class);
- (j) There is a class consisting of all dependants of members of the Patient Class, as defined by Section 61 of the *Family Law Act*, RSO 1990, c F.3, s.61 and similar legislation in other Provinces, as listed in Schedule “A”, where applicable (the Family Class);
- (k) The Patient Class is objectively defined, with membership comprised of those who were implanted by the listed models of Defibrillators manufactured between January 10, 2010 and May 23, 2015;
- (l) The Family Class is objectively defined, with membership comprised of those who are dependents of members of the Patient Class according to the criteria set out by Section 61 of Ontario’s *Family Law Act*, RSO 1990, c F.3, s.61, and similar legislation in other provinces;

- (m) The class definition of the Patient Class and of the Family Class is not overly broad;
- (n) There is a rational relationship between the Patient Class, Family Class, and the proposed common issues;
- (o) The claims asserted in the Amended Statement of Claim raise common issues, the determination of which will move the litigation forward substantially;
- (p) A class proceeding is the preferable procedure for the resolution of the common issues and meets the goals of the *CPA*;
- (q) The Patient Class consists of over 8,000 members;
- (r) The proposed representative plaintiff, Shirley Houle, can fairly and adequately represent the interests of the Patient Class and has no conflict with the Patient Class on the common issues;
- (s) The proposed representative plaintiff, Roland Houle, can fairly and adequately represent the interests of the Family Class and has no conflict with the Family Class on the common issues;
- (t) The proposed representative plaintiffs and Class Counsel have produced a workable litigation plan for advancing the claims on behalf of the class up to the common issues trial and afterwards;
- (u) The proposed representative plaintiffs and Class Counsel have a reasonable notice program for notifying class members of certification of the action as a class proceeding;

- (v) S. 5 and 6 *CPA*;
- (w) Rule 37 of the *Rules of Civil Procedure*;
- (x) S. 61 *Family Law Act*; RSO 1990, c F.3;
- (y) The *Fatal Accidents Act*, CCSM, c F50;
- (z) The *Fatal Accidents Act*, RSS 1978, c.F-11;
- (aa) The *Fatal Accidents Act*, R.S.A. 2000, c F-8;
- (bb) The *Family Compensation Act*, RSBC 1996, c 126;
- (cc) The *Fatal Accidents Act*, RSNL 1990, c F-6;
- (dd) The *Fatal Injuries Act*, RSNS 1989, c 163;
- (ee) The *Fatal Accidents Act*, RSPEI 1988, c.F-5
- (ff) The *Fatal Accidents Act*, SNB 2012, c 104; and
- (gg) such further and other grounds as counsel advises and this Court permits.

THE FOLLOWING DOCUMENTARY EVIDENCE will be used at the hearing of the motion:

- (a) The affidavit of Shirley Houle sworn November 21, 2017;
- (b) The affidavit of Roland Houle sworn November 21, 2017;
- (c) The affidavit of John Kingman Phillips sworn November 22, 2017;
- (d) The affidavit of Dr. Kenneth Ellenbogen sworn November 9, 2017;

- (e) The affidavit of Dr. Ulrich von Sacken sworn October 17, 2017; and
- (f) Such further and other evidence as counsel may advise and this Honourable Court may permit.

DATED: November 22, 2017

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Court File No. CV-17-512508-00CP

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