EXHIBIT C

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No. 2022-38664

RICKY MARSHALL, Plaintiff	§	IN THE DISTRICT COURT OF
V.	§	HARRIS COUNTY, TEXAS
MEDTRONIC, INC. Defendant	§	11th _____ JUDICIAL DISTRICT

PLAINTIFF'S ORIGINAL PETITION

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, Ricky Marshall, plaintiff, complaining of Medtronic, Inc., defendant, and for cause of action would show as follows:

I.

This case should be governed in accordance with the Discovery Control Plan found in Rule 190 of the Texas Rules of Civil Procedure (Level 3).

II.

Ricky Marshall ("Marshall") is an individual residing in Houston, Harris County, Texas.

Medtronic, Inc., a subsidiary of Medtronic PLC ("Medtronic"), is a foreign corporation with its principle operational offices located at 710 Medtronic Parkway, Minneapolis, Minnesota 55432-5604. Medtronic is and has been doing business in the State of Texas. Medtronic may be served with process through its agent for process, Corporation Service Company d/b/a CSC-Lawyers Incorporating Service Company 211 E. 7th Street, Suite 620, Austin, TX 78701-3136 USA.

III.

Marshall seeks to recover damages he has sustained due to a defective LVAD pump system, sometimes referred to as the HeartWare HVAD device ("HeartWare device"), manufactured and sold by Medtronic that was implanted in Marshall's chest by Saram Nathan, M.D. at Memorial Hermann Hospital, Houston, Harris County, Texas, on June 4, 2020. Marshall was discharged from

Memorial Hermann Hospital on June 29, 2020. Marshall underwent this implant surgery due to end-stage heart failure from which he was suffering. He understood at the time of his surgery the HeartWare device would assist his own circulatory system by pumping blood from his damaged heart. The Heartware device would keep Marshall alive until he was approved for and could undergo a heart transplant procedure.

IV.

Medtronic abruptly pulled its HeartWare device from the market in late May, 2021, less than a year after the device was implanted in Marshall's chest. The action undertaken by Medtronic came as a result of numerous Class I recalls and reports of patient injuries and deaths associated with the device. Prior to the implant surgery involving Marshall, there was great concern with the Medtronic HeartWare device regarding ongoing failures and a "growing body of observational clinical comparisons indicating a higher frequency of neurological adverse events, including stroke, and mortality with the Heartware device as compared to other circulatory support devices available to patients." At the time Medtronic stopped selling the HeartWare device, approximately 4,000 patients had the device implanted, including Marshall. Moreover, Medtronic advised against elective explants of the HeartWare device due to potential health risks to the patient. A patient such as Marshall was as likely to die from removal of the HeartWare device as he was if the device remained in his body.

V.

Marshall seeks damages from Medtronic, under two theories of recovery, namely:

(1) Products liability based upon:

(a) Manufacturing defect;

(b) Design defect; and

(c) Marketing defect.

(2) Negligence in the marketing and the manufacturing of the HeartWare device manufactured and sold by Medtronic, which is the subject of this lawsuit; additionally, invoking the negligence doctrine of *res ipsa loquitur*.

VI.

When it is alleged that Medtronic committed an act or practice, or by omission failed to act, it is meant that Medtronic acted or failed to act by and through its agents, servants and employees whose acts or omissions were within the scope of their authority or employment.

VII.

The cause of action giving rise to this lawsuit, that is, the claims for damages for the injuries sustained by the plaintiff as a result of Medtronic's wrongdoing, arose in Harris County, Texas.

VIII.

Medtronic was at the time of this occurrence and was the major designer, manufacturer and marketer of the HeartWare device. Additionally, at all times pertinent hereto, Medtronic was a merchant with respect to the HeartWare device within the meaning of TEX. BUS. & COM. CODE § 2.314. Medtronic was, at all times pertinent hereto, the marketer and seller of the HeartWare device.

IX.

Medtronic's decision to pull the HeartWare device from the market followed a series of Class I recalls, including three in 2021 alone, resulting in reports of 91 injuries and 15 deaths of patients with the implanted device. The Federal Drug Administration (FDA) advised healthcare providers in late May, 2021, to cease new implants of the HeartWare device system, indicating that Medtronic had "received over 100 complaints involving delay or failure to restart of the HeartWare device, including reports of 14 patient deaths and 13 cases where an explant was necessary."

Medtronic had acquired the HeartWare device was part of its $1.1 billion acquisition of HeartWare International in 2016. The device was intended to help patients suffering from heart failure pumping blood through their bodies. The system, which included an implantable pump and non-implantable components, is a Class III medical device, meaning it constitutes a high risk and can pose a significant risk of injury to patients.

Since the HeartWare device received premarket approval in November, 2012, the FDA has issued 13 Class I recalls involving multiple parts and components of the pump. Issues and malfunctions ranged from devices failing to restart to the company needing to update instructions for use and patient manuals. While some recalls predate Medtronic's acquisition, nine Class I recalls have come since Medtronic bought HeartWare.

Along with numerous recalls, the HeartWare device has received thousands of reports of patient injuries, deaths and device malfunctions in the FDA's Manufacturer and User Facility Device Experience (MAUDE) database. An analysis of MAUDE data by the watchdog group ECRI showed Medtronic's HeartWare device had a higher rate of device malfunction than comparable devices marketed by rival companies.

X.

Marshall's HeartWare device was not intended to be defective and cause unanticipated or unnecessary delays or failures to restart the pumping of blood. Such a defect was not intended to be part of the HVAD pump design or purpose. As a result, Marshall has sustained both physical and mental damages, particularly the mental stress of having an implanted device that is very unreliable and cannot be removed due to the lethal risk of explantation.

XI.

Medtronic has removed the HeartWare device from the market due to its use being associated with increased risks of mortality. Patients, such as Marshall, who have been implanted

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