Report Form
Manufacturer's Field Safety Corrective Action Report

Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 8)

v.01.13

1. Administrative information	
To which NCA(s) is this report being sent? Danish Health & Medicines Authority, Pharmacovigilance and Medical Devices Att. Ms. Kristine Rasmussen, Axel Heides Gade 1 2300 Kobenhavn, Denmark	
Type of report ☒ Initial report ☐ Follow up report ☐ Final report	
Date of this report 20 March 2024	
Reference number assigned by the manufacturer FA1364	
FSCA reference number assigned by NCA -	
Incidence reference number assigned by NCA -	
Name of the co-ordinating national competent authority (if applicable) IGJ (Dutch) Health and Youth Care Inspectorate – ref: IT2092155	
2. Information on submitter of the report	
Status of submitter ☐ Manufacturer ☐ Authorised representative within EEA, Switzerland and Turkey ☒ Others (identify the role): Quality and Regulatory Affairs Specialist, Nordic Countries.	
3 Manufacturer information	
Name Covidien llc	
Contact name -	
Address 15 Hampshire Street	
Postcode 02048	City Mansfield, Massachusetts
Phone .	Fax .
E-mail .	Country USA
4 Authorised representative information	
Name Medtronic B.V.	
Contact name Inge Vandenbussche	

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5 National contact point information	
National contact point name Medtronic AB	
Name of the contact person Marie Christensen	
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6 Medical device information	
Class ☐ AIMD Active implants ☐ MDD Class III ☒ MDD Class IIb ☐ MDD Class IIa ☐ MDD Class I ☐ IVD Annex II List A ☐ IVD Annex II List B ☐ IVD Devices for self-testing ☐ IVD General	
Nomenclature system (preferable GMDN) EMDN	Nomenclature code Z12020101
Nomenclature text ROBOTIC-ASSISTED ENDOSCOPIC SURGERY SYSTEMS	
Commercial name/ brand name/make Hugo™ RAS Surgeon Console	
Model number MRASC0001	Catalogue number N/A
Serial number(s) C21AJH0114, C21AJK0136, C22AJC0168, C22AJC0177, C22AJD0185, C22AJE0196, C21AJB0078.	lot/batch number(s) N/A
Device Manufacturing date N/A	Expiry date N/A
Software version number (if applicable) N/A	
Accessories/associated device (if applicable) N/A	
Notified body (NB) ID- number 2797	
7 Description of FSCA	

Background information and reason for the FSCA

Device description:
Hugo™ Robotic-Assisted Surgery (RAS) is a modular robotic platform for performing robotically assisted, minimally invasive surgery (MIS). It enables the surgeon, sitting at an ergonomically adjustable surgeon console, to view the surgical field in 3D and control movements of the endoscope and instruments with individual arms at the surgical table. It also allows surgeons and OR teams to manually control arms at the bedside, including using one arm as an endoscope holder.
The surgeon console is the surgeon's interface for controlling the Hugo™ RAS System. The surgeon console includes two hand controllers, a flat screen 3-D display and 3-D glasses to view the endoscope image and status information, a small, interactive touchscreen to control settings and selections, and foot pedals that enable control of the endoscope, and repositioning of the hand controllers, and activation of electrosurgical energy. For Hugo™ RAS system configuration information, Instructions for Use, indications, contraindications, warnings, and precautions, refer to the Hugo™ RAS system user guide.
These products are to be used by medical professionals qualified in the transportation, preparation, and use of surgical devices. The Hugo™ RAS system is intended for use in a sterile operating room environment.

Indications for Use
The Hugo™ Robotically Assisted Surgery (RAS) System is intended to assist in the accurate control of instruments and accessories including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, forceps/graspers, needle holders, endoscopic retractors, electrosurgical tools and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrosurgery, and suturing during urologic surgical procedures, gynecologic laparoscopic surgical procedures, and general laparoscopic surgical procedures. The system is indicated for adult use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative surgical procedures set forth in the User's Guide.

Description of Issue:
At the time of the initial Issue Impact Assessment (IIA), it was understood that the issue of the paddle J8 actuating by itself, resided with the Galil Motor Controller (PT00004227). After working with Galil to understand the cause of failure within the design and manufacturing process, Medtronic released an engineering report which summaries the conclusions of the Galil investigation. It is with this evidence that supports the scope of issue provided by Galil and gives Medtronic the necessary evidence to move forward with a field action. During this process preventative maintenance cycles within the field were replacing these components on a regular basis, at an interval of every 75 procedures. From the failed units that were documented in the 3 complaints received, those units had performed 260 cases, 277 cases, and 690 cases respectively prior to the controller failure. By ensuring that the units were replaced at regular preventive maintenance service intervals of 75 procedures, the risk that additional fielded unit's controllers would fail was mitigated.

Summary of Health Hazard Analysis:
The three (3) reported events originated from Belgium (1), Spain (1) and Japan (1).

Hazard:
- Uncommanded motion of instrumentation within the patient

Associated potential Harms:
- Tissue Damage/Tissue Trauma; Severities 5,4,3,2,1
- Bleeding; Severities 5,4,3,2,1

The overall patient risk falls into Medium/Zone 2. Each patient harm is dependent on the hazardous situation, individual use cases, and patient factors influencing the end outcome.

Description and justification of the action (corrective/preventive)
An FSN will be delivered to affected HCP's to notify them of the issue. Medtronic representatives will schedule a service call to inspect the impacted product and will service the device within the coming months.

Advice on actions to be taken by the distributor and the user:
- Immediately notify all personnel in all care environments in which the Hugo™ RAS system is used about this Urgent Field Safety notice.
- The continued use of Hugo™ RAS System is considered appropriate based on an internal review taking into account the benefit provided to patients compared to any potential risk that may be posed. This assessment may be augmented in individual surgeries by determining any circumstances that materially change the benefit or risk.
- To mitigate any unintended motion, the user would restrain the hand controller lever from actuating and then immediately disengage teleoperation.
- Please post this notification in a prominent location and maintain awareness of this matter until the issue is resolved.

Progress of FSCA, together with reconciliation data (Mandatory for a Final FSCA)

Attached please find	FSN Status
☒ Field Safety Notice (FSN) in English ☐ FSN in national language ☒ Others (please specify): Customer List in your country	☐ Draft ☒ Final

Time schedule for the implementation of the different actions

This FSCA will be initiated 20 March 2024 and is planned to be completed by 19 August 2024.

These countries within the EEA and Switzerland and Turkey are affected by this FSCA

- within the EEA, Switzerland and Turkey:

☐ AT	☒ BE	☐ BG	☐ CH	☐ CY	☐ CZ	☒ DE	☒ DK	☐ EE	☒ ES
☐ FI	☐ FR	☒ GB	☐ GR	☐ HU	☐ IE	☐ IS	☒ IT	☐ LI	☐ LT
☐ LU	☐ LV	☐ MT	☐ NL	☐ NO	☐ PL	☐ PT	☐ RO	☐ SE	☐ SI
☐ SK	☐ TR	☐ HR							

☐ All EEA, Candidate Countries, Switzerland and Turkey

- Others:

Comments:
MDR Risk class: IIb. Classification Rule: Annex VIII, Rule 9. UDI-DI: 0763000B00006347V.

In Denmark, 1 system will be serviced as part of this FSCA.

I affirm that the information given above is correct to the best of my knowledge.

Marie Christensen
……
Signature

Marie Christensen	Stockholm	20 March 2024
Name	City	Date

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorized representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.