1- Internal Audit information:

Activities Audited	Distribution of Devices with Appropriate Marketing Authorization, Device Marketing Authorization and Facility Registration ISO 13485:2016: 4.1.1, 4.2.1, 5.2, 7.2.1, 7.2.3, 7.3.9, CMDR 26, 34, 43.1 Australian TGA 1989, Parts 4-2, 3, 4, 9 and Chapter 5, TG(R)), Division 5.2 Schedules 1, 2 and 3, 21 CFR 807 MDSAP Chapter 2, Tasks 1-3
Audit Date(s)	2024-06-0
Audit Date scheduled (*as per Audit schedule*)	June 10, 2024
Internal Auditor(s)	Gordon Forest, VL Solutions Inc.
Employees audited	Tabitha Jaramillo, Fatima Chaouki
Department Manager	Étienne Lefort

2- Audit Summary:

Device marketing authorization: I verified that the devices were properly authorized for commercial distribution in the following markets:

a) Canada – Health Canada MD Active Licence Listing

The following device licence was issued for TREMOFLO AIRWAVE OSCILLOMETRY SYSTEM, Licence No. 92761, Class 2, Revision Date: 2024-06-07

Device Name	Identifier first issue date	Device Identifier
TREMOFLO C-100 AIRWAVE OSCILLOMETRY SYSTEM - ALK PFT FILTER	2014-02-05	101419
TREMOFLO C-100 AIRWAVE OSCILLOMETRY SYSTEM - CLEARFLO F-100 PFT FILTER	2014-02-05	101421
	2021-07-30	101635
TREMOFLO C-100 AIRWAVE OSCILLOMETRY SYSTEM - SRG PFT FILTER	2014-02-05	101325
TF C100 CALIBRATED REFERENCE LOAD	2021-07-30	100986
	2021-07-30	101059
	2024-04-23	101969
TF C100 SYSTEM & ACCESSORIES	2021-07-30	101524
	2021-07-30	101963
	2021-07-30	101969
	2023-10-26	102110

	2024-03-13	102002
	2024-03-13	102189
	2024-03-13	102189
	2024-04-23	101762
	2024-04-23	102079
TF C100 UNIT - CLEARFLO PFT FILTER COMPATIBLE	2021-07-30	101336
TFC100 SUPPORT ARM - ASSEMBLY	2021-07-30	101923
TREMOFLO C100 SOFTWARE	2021-07-30	V1.0
	2023-01-18	V1.9
	2024-03-13	V1.2
TREMOFLO C100 SOFTWARE V1.0 & DIGITAL USER MANUAL.	2022-05-25	101503
TREMOFLO C2 AIRWAVE OSCILLOMETRY SYSTEM	2022-05-25	101711
TREMOFLO C2 AIRWAVE OSCILLOMETRY SYSTEM & ACCESSORIES	2022-05-25	101929
	2022-05-25	102035
	2022-05-25	102036
	2024-03-13	102185
TREMOFLO C2 SENSOR MODULE	2022-05-25	101664
TREMOFLO C2 SUPPORT ARM	2022-05-25	101688
TREMOFLO CALIBRATED REFERENCE LOAD	2023-01-18	101947

I have determined that the device licencing with Health Canada for both the TremoFlo C-100 and TremoFlo C2 (including accessories) meets the regulatory requirements.

The following procedure regarding significant change notification to Health Canada: QMS Procedure No.: QP16 Significant and non-significant Change Notification to Regulatory Authorities, Rev. 9.0. No-significant changes were issued to Health Canada:
Feb 2024: For example, a change was made to the CMDR device licence, since the United Arab Emirates (UAE) requires that the device (Kits) appears on the Health Canada licence. To conform to this request, Software 1.0, Software 1.2, catalog Nos. 102002 and 102189 (C-100 system and accessories for the UK) were added to the Health Canada medical device active licence listing. I have verified that these catalog numbers were added to the Health Canada Licence (2024-03-13).

A second non-significant change was made on new test load 102069 and two kits nos. 101762 and 102079. I have verified that these catalog numbers were added to the Health Canada licence 23/04/2024.

In addition, the medical devices have an electrical certificate of compliance: Original Report Reference No. 102927294BOX-002 (2027-03-06) for IEC 60601-1: 2005 (third edition) + CORR 1: 2006 + CORR. 2: 2007+A1: 2012 (or IEC 60601-1: 2012 reprint and amendment M1: 2019-08-15. Document #80039566 issued 2021-12-24 for medical device equipment Airway Oscillometry System, Model/Type: TremoFlo C2, stating that they are eligible to bear the CSA Mark with indicators 'C' and 'US' under IEC 60601-1 3rd edition.

b) United States – Establishment Registration and Device Listing

Proprietary Name:	TremoFlo C-100 Airwave Oscillometry System
Classification Name:	IMPEDANCE MEASURING DEVICE UTILIZING OSCILLATION TECHNIQUES
Product Code:	PNV
Device Class:	2
Regulation Number:	868.1840
Medical Specialty:	Anesthesiology
Registered Establishment Name:	THORASYS THORACIC MEDICAL SYSTEMS INC.
Registered Establishment Number:	3011331794
Premarket Submission Number:	K170185
Owner/Operator:	THORASYS Thoracic Medical Systems Inc.
Owner/Operator Number:	10056503
Establishment Operations:	Manufacturer

Proprietary Name:	tremoflo C2 Airwave Oscillometry System
Classification Name:	IMPEDANCE MEASURING DEVICE UTILIZING OSCILLATION TECHNIQUES
Product Code:	PNV
Device Class:	2
Regulation Number:	868.1840
Medical Specialty:	Anesthesiology
Registered Establishment Name:	THORASYS THORACIC MEDICAL SYSTEMS INC.
Registered Establishment Number:	3011331794

Premarket Submission Number:	K221024
Owner/Operator:	THORASYS Thoracic Medical Systems Inc.
Owner/Operator Number:	10056503
Establishment Operations:	Manufacturer

I have determined that both the TremoFlo C-100 and TremoFlo C-2 have been adequately registered with the FDA and that Thorasys Medical Device Systems Inc. is registered. It is also noted that both airway oscillometry devices have premarket notification via 510(k): K170185 (TremoFlo C-100) and K221024 (TremoFlo C2).

Thorasys' US Agent is Registrar Corp. (David Lennarz).

c) Australia: Australian Register of Therapeutic Goods (ARTG):

Bird HealthCare Pty Ltd – Pulmonary function analysis system, adult (TremoFlow C100 and C2, ARTG ID: 220187) entry for Class IIa medical device is listed as active. The GMDN is 35282. Certification number(s) : DV-2014-MC-01649-1.

As medical devices marketed in Australia require a Declaration of Conformity (DoC), I verified that one had been drawn up.

Manufacturer's Declaration of Conformity, Rev. 4.0 DOC No. REC-102893: under clause 8 of Schedule 3 to the TG(MD)R 2002. Approved C. McLaren: 06/07/2023.

I verified that QP16 Rev. 9.0 Regulatory Processes (effective 14/03/2024) was updated to include the clinical evaluation requirements with respect to the Australian regulation.

Thorasys has documented a Clinical Evaluation Plan and a Clinical Evaluation Report (CER) in accordance with the therapeutic Goods (Medical Devices) Regulations, Schedule 3 (conformity assessment procedures), part 8 (Clinical Procedures). The clinical evaluation plan and clinical evaluation report must be updated throughout the lifecycle of the product and demonstrate the product's continued compliance to the Essential Principles as per the TG(MD)R 2002, Schedule 1 (Essential Principles). Reference: QP03, Rev. 8.0 Design Control (31/01/2024).

In addition, QP16, Rev 9.0 Regulatory Processes (effective 14/03/2024) was updated to include the clinical evaluation requirements with respect to the Australian regulation.

As per CAPA-100136, a new section (7.2) was added to the above procedure, «Notifying Regulatory Authorities and Sponsors» and change the section that was previously in 7.2 «Investigation of the problem» to Section 7.3 Update recall contacts. The recall procedure for Australia, QP24, Rev. 2.0 (30/04/2024), was updated to include the following process requirement:

- Notification requirements to sponsor with respect to recall activities performed in Australia.
- Notification requirements to regulatory authorities with respect to recall activities performed in Australia.

d) European Union: MDD (for TremoFlo C100 – legacy device) CE Certificate 6077250 – Notified Body confirmation letter: ensures extension to 31/12/2028.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The **PRRC** is Étienne Lefort. An assignment letter was issued under the job description for Head of Regulatory Affairs. There are specific responsibilities assigned for the PRRC which include ensuring the conformity of devices, ensure that technical documentation and the EU DoC are drawn up and kept up-to-date, ensure that post-market surveillance obligations are complied with (Article 10(10) of MDR2017/745, ensure the reporting obligations referred to in Articles 87 to 91 of the MDR/2017-745 are fulfilled, and in case if investigational devices, ensure the statement referred to in Section 4.1 of Chapter II of Annex XV of MDR/2017-745 is issued.
The device is marketed under the MDD, Class IIa, Notified Body: BSI (Netherlands) – DoC Thorasys document # REG 102247, Rev. 14.

Model C2 is not currently CE-marked.

In addition to the above markets, the C100 model is also marketed in:

e) **Mexico** – certificate of registration 0011E2020 from COFEPRIS – Mexico.

f) **Israel** – C-100: original registration # 39430001 (Oct. 2022) and confirmation # 33758 from Ministry of Heath, Israel. The registration will be up for renewal in October 2024.

g) **India**: Central Drugs Standard Control Organization, directorate General of Health Services, Ministry of Health and Family Services (Medical Device and Diagnostic division) File No; HO/MD//2022/002461, Import Licence under the Medical Device Rules, 2017 (31/03/2023).

h) **UK**: Assignment of UK representative and Thorasys registrations with MHRA completed 8 January 2024, an extension for the CE certificate, 607250, was due to expire on or after 20 March, 2024 and remains valid by virtue of EU MDR Article 102(2), was granted to 30/06/2028. Application references 2022010301230819 (for

PFT filters and nose clips) and 2022010302230820 (for TremoFlo C100 system). This allows continued acceptance of the current MDD CE Mark & Certificates for these products to be distributed in the UK until June 30, 2028 (updated per update MDR transitional dates). The EUAR is OMC NI Medical Limited, located in Belfast, Northern Ireland. The representative agreement, UK registration No. 12409343, with its registered office at Planet House, North health lane, Horsham, West Sussex, RH12 5QE (OMC). Effective date: 1/12/2021.

i) **Switzerland**: Swissmedic (Swiss Agency for Therapeutic Products) Registration was completed on April 11, 2022 (confirmed by email).

Notification of changes to marketed devices or to the QMS.

I have verified that Thorasys has developed and implemented procedures to manage changes to marketed devices or to its QMS and have not detected any discrepancies with this process. No design changes were detected that could have required notification to the jurisdictions in which the devices are marketed.

With regards to the TremoFlo C2 model, the proper authorizations/licences were obtained. In the United States, the C2 is predicated on the C100 device (K221024).

MHRA Registration confirmation Letter: March 20, 2024. Application to register or update an existing registration for the following manufacturer, which you submitted on 20 March 2024 has been reviewed. Application Reference: 2024032002350108, for GMDN code 35282 – Pulmonary function analysis system, adult. Thorasys maintains an Excel file which lists all the Devices, accessories and software associated with GMDN 35282 available in the UK.

3- Non-Conformities:

- **NC#ID:** NCxx
- **Category:** Minor ☐ Medium ☐ Major ☐
- **NC Description** (including reference and evidence):

No non-conformities were detected for this process.

4- Opportunities For Improvement:

No opportunities for improvement were detected for this process

Documented /Approved by	Name:	Signature:	Date:

Department Manager	Etienne Lefort Etienne Lefort Signer ID: HEBIXXRYNS... 25 Jul 2024, 12:16:54, EDT Signing Reason: I approved this document	25-Jul-2024 EDT
Quality Assurance	Tabitha Jaramillo Tabitha Jaramillo Signer ID: INFXWXQWVX... 25 Jul 2024, 13:33:23, EDT Signing Reason: I approved this document	25-Jul-2024 EDT

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Author:	Fatima Chaouki	Creation Date:	10 Jul 2024, 10:16:07, EDT	Completion Date:	25 Jul 2024, 13:33:23, EDT

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Name: Internal Audit Report Design and Development Process - June 2024

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Type:

Document Ref: 35eb680dbd1a9232d0e91a198247763e268c61b1c634d9ec53b5fb604075316e

Document Total Pages: 7

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Document Total Pages: 24

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Document Total Pages: 3

Name: Internal Audit Report Production and Service Controls Process - June 2024

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Document Total Pages: 10

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Document Total Pages: 7

Name: Internal audit summary report - 2024 - Corrected

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Document Total Pages: 2

Document Signed By:

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11 Jul 2024, 15:51:33, EDT
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