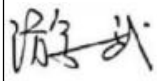
Clinical Evaluation Report

Product n ame:	Air Compressi on Therapy System
Model:	DC battery model: FO3002,FO3002B,FO3002C,FO3002D,FO3002A,FO3002E,FO3002-1,FO3002B-1,F03002C-1;
Docume nt type:	CE Tech ni cal Docume nt
Docume nt No.:	HF- FO3001-CER -001
Versio n:	V1.0

Role	**Signature**	**Date**
Prepared by		2023-07-07
Reviewed by		2023-07-09
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Revision Record

Revision history				
No.	**Version**	**Author**	**Date**	**Description**
1	V1.0	You wu	2023-07-10	First issue

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1. General principles and goals

1.1 General principles

Clinical evaluation means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer. Clinical evaluation is an ongoing process conducted throughout the life cycle of a medical device.

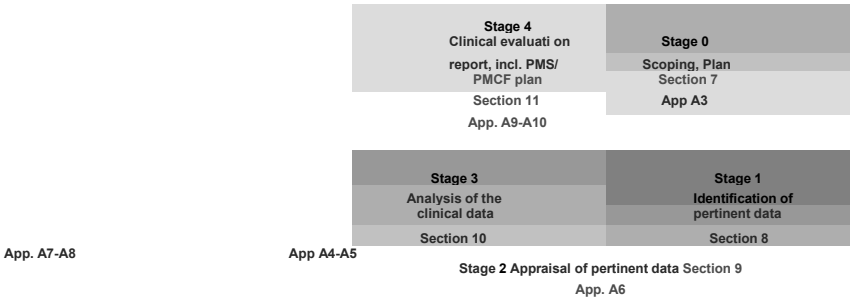
In exceptional cases where an instruction for use is not required, the collection, appraisal, and analysis are conducted taking into account generally recognised modalities of use.

The requirements for clinical evaluation apply to all classes of medical devices. The evaluation should be appropriate to the device under evaluation, its specific properties, and its intended purpose.

Benefits and risks should be specified, e.g. as to their nature, probability, extent, duration and frequency. Core issues are the proper determination of the benefit/risk profile in the intended target groups and medical indications, and demonstration of acceptability of that profile based on current knowledge/ the state of the art in the medical fields concerned.

Clinical evaluation is first performed during the conformity assessment process leading to the marketing of a medical device and then repeated periodically as new clinical safety and performance information about the device is obtained during its use. This information is fed into the ongoing risk analysis and may result in changes to the Instructions for Use.

The general process of clinical evaluation:



1.2 Goals

This clinical evaluation is aimed to:

Identify and discuss any literature data, aimed for a similar indication that support the safety and performance claims. Clinical evaluation is the assessment and analysis of clinical data pertaining to a medical device in order to verify the clinical safety and performance of the device.

Present the clinical safety and effectiveness and demonstrate the conformity of the product to Annex 1 “General Safety and Performance Requirements” of Medical Device Regulation 2017/745/EU.

We reviewed below several aspects, the compliance to harmonized standards, intended applications/indications/ claims, substantially equivalence comparison to the equivalent/equivalent device, and the evaluation of relevant scientific literatures, the clinical data analysis of data and appraisal.

2. Medical device name, model and type

2.1 Medical device name and model

Air Compression Therapy System: FO3001, FO3008, FO3001B, FO3001C

2.2 Intended purpose

The product is indicated for use by medical professionals and patient at home, who are under medical supervision, reducing swelling and preventing thrombosis in the lower extremities or treatment of truncal or arm breast cancer-related lymphedema, such as: Primary lymphedema, edema following trauma and sport injures, post-immobilization edema, Venous insufficiencies, Lymphedema.

The system can be used at home or in hospital, to patients who are over 18 years old.

2.3 Explanation of any novel features

1) Novel Product Yes □ No 0
2) Novel related clinical procedure Yes □ No 0
3) Explanation of any novel features

No novel features.

3. Clinical evaluation report authors

0 CER dated and signed, please see first page
0 CVs provided for CER author(s), please see attached CVs for details

3.1 Author qualification of this clinical evaluation report

The clinical evaluation is conducted by a suitably qualified team, which includes experienced RA who is familiar with regulatory requirements, and experienced professionals who graduated from medical schools and worked as doctors. Each member of this team fulfill part of the clinical evaluation work.

In general, this team can cooperative together and possess knowledge of the following:

1) information management

Note: experienced professionals in this team are with scientific background or librarianship qualification, and experience with relevant databases);

2) regulatory requirements; and

Note: RA in this team is specialized in medical device registration and QMS management, and familiar with regulatory requirements, including registration requirement, clinical evaluation requirement, and specific standards.

3) medical writing

Note: experienced professionals in this team are with post-graduate experience in diagnosis and treatment of tumors. They received sufficient training at school and during work. Meanwhile, they are experienced in medical writing, systematic review and clinical data appraisal.

4) All members in this team gained the technology and its application.

5) Experienced professionals are experienced in management of the conditions intended to be diagnosed by the device, knowledge of medical alternatives, treatment standards and technology.

3.2 Evaluator

No.	Person	Remark

1	Compiler		Regulatory engineer
2	Reviewer		Clinician / doctor
3	Approver		Product project manager

CV of evaluator
See appendix 1

3.3 Declaration of interest

See appendix 2

4. Clinical evaluation plan

To confirmation of conformity with relevant general safety and performance requirements set out in Annex I of MDR (EU) 2017/745, the clinical evaluation plan was established in the initial stage of development, which intended to define the schedule and how to perform clinical evaluation throughout the life cycle according to the requirements of article 61 MDR (EU)2017/745, detail see separate clinical evaluation plan.

5. An identification of the general safety and performance requirements that require support from relevant clinical data

The general safety and performance requirements that require support from relevant data are listed below:

GSPR 1. Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high.

GSPR 8. All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.

6. Common specifications and harmonized and other standards applied

6.1 Common specifications

There is no common specification for the product.

6.2 Harmonized standards relevant to the clinical evaluation of the device under evaluation

Serial Number	Title	Purpose is to prove	File number
EN ISO 20417:2021	Medical devices - Information supplied by the manufacturer with medical devices	IFU	
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	Labeling	
EN SO 14971:2019+A11:2021	Medical devices — Application of risk management to medical devices	Risk man ageme nt	
CEN ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020)		
EN 60601-1:2006+A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Electrical safety	
EN 60601-1-2:2015+A1:2021	Medical electrical equipment part 1: General requirements for safety 2:Collateral standard: Electromagnetic compatibility — requirements and test	Electromagnetic compatibility	
EN 60601-1-6:2010 +A12015+A2:2021	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	Usability	
EN 62366-1:2015+A1:2020	Medical devices - Application of usability engineering to medical devices	Usability	

6.3 Other solutions that have been applied

Considering the device has other safety issues such as the continuous performance after transportation, and no relevant harmonized standards exist, so we identify and apply relevant international standards to demonstrate the safety. Application of such kind of standards will not

raise new risks.
Meanwhile, we also apply various guidance such as MDCG 2020-5, 2020-6, 2020-7, 20208 and MDCG 2020-13, as supporting standards when conducting clinical evaluation.

Standard number	Title	Purpose is to prove	File Number
MEDDEV 2.7-1 rev. 4	Clinical evaluation: A guide for manufacturers and notified bodies	Guidance for clinical evaluation	
MDCG 2020-5	Guidance on Clinical Evaluation - Equivalence		
MDCG 2020-6	Regulation (EU) 2017/745: Cli nical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC		
MDCG 2020-13	Clinical Evaluation Assessment Report Template		
ISTA 2A:2011	Packaged-Products weighing 150 lb (68 kg) or Less	Transportation	
MDCG 2020-7	Guidance on PMCF Plan Template	PMCF	
MDCG 2020-8	Guidance on PMCF Evaluation Report Template		

7. Demonstration of equivalence

7.1 Clinical evaluation route based on peer reviewed scientific literature

Equivalence route, since

1) There is sufficient clinical data to demonstrate conformity of the modified device with the relevant safety and performance requirements.
2) Technology is the proven technology and is well accepted by the medical community.

Therefore, assessment of safety and performance of the devices in scope is based on several data sources, including internal clinical studies, compliance with recognized standards, verification analyses as well as clinical data from the relevant published peer- reviewed clinical literature. So, the clinical evaluation is based on data related to device under evaluation and equivalent devices.

7.2 Clinical data source of peer reviewed scientific literature

No	Data source	Website	Reason of choosing the data source
1	Pubmed	http://www.ncbi.nlm.nih.gov/sites/entrez	PubMed remains the most popular search engine used to retrieve original studies, which contains journals more than 6000, mainly involving medical, biomedical, sciences and clinical core journals, updated every day, can get particular topic tracking, and return to around 5% of the peripheral related results (i.e., false positive), it is easy to search, and can be mixed and combined to search to meet the recall rate and accuracy rate
2	Springer	http://link.springer.com/	with possibly incomplete coverage of European Journals and comprehensiveness may not necessarily be guaranteed, so Springer which can be used as supplements. Springer contains electronic full-text of nearly 2,900 journals covering 13 disciplines, the system is a comprehensive database. In addition to medicine, there are other non-medical catalogues that may also include medicine-related journals.
3	Elsevier Science Direct	https://www.sciencedirect.com/	Elsevier ScienceDirect, the world's largest platform dedicated to peer-reviewed primary scientific and medical research, hosts more than 20 million pieces of content from over 4,600 journals and over 45,000 eBooks and receives more than 18 million visitors a month. Elsevier has continued to invest in ScienceDirect and integrate new remote access methods to give researchers the ability to easily use its tools when working from home, safe in the knowledge that they are doing so securely, and that their privacy and data are protected.

7.3 Information of equivalent device

Manufacturer:

Name: Compression System

Model: PT1002

Brief Description:

7.4 Equivalence table

No.	Item	Subject device	Equivalent device	Similar or same

1	Device name	Air Compression Therapy System	Compression System	/
2	Model	FO-3001	PT1002 0123	/
3	Intended use	The product is indicated for use by medical professionals and patient at home, who are under medical supervision, reducing swelling and preventing thrombosis in the lower extremities or treatment of truncal or arm breast cancer-related lymphedema, such as: Primary lymphedema, edema following trauma and sport injures, post-immobilization edema, Venous insufficiencies, Lymphedema.	The product is indicated for use by medical professionals and patient at home, who are under medical supervision, reducing swelling and preventing thrombosis in the lower extremities or treatment of truncal or arm breast cancer-related lymphedema, such as: Primary lymphedema, edema following trauma and sport injures, postimmobilization edema, Venous insufficiencies, Lymphedema.	Same
4	Environment of use	be used at home or in hospital	be used at home or in hospital	Same
5	Patients treated areas	Leg, foot	Leg, foot	Same
6	Patient population	patients who are over 18 years old	patients who are over 18 years old	Same
7	Power Requirements	AC 220-240V, 50-60Hz, 65VA	100-240 VAC, 50VA, 50/60 Hz	Similar
8	Compression Type	Leg Sleeves: Sequential, Gradient Foot Cuffs: Uniform	Leg Sleeves: Sequential, Gradient Foot Cuffs: Uniform	Similar
9	Size	240 x 200 x 120mm	Height: 6.2 inches (15.8 cm) Width: 7.0 inches (17.8 cm) Depth: 4.5 inches (11.4 cm)	Similar
10	Set Pressure	30~250mmHg	20-250mmHg	Similar
11	Sleeve size	L: 100 x74cm 仃 02-04) XL: 110 x70cm (T03-04) XXXL: 125 x76cm (T05-04)	Waist sleeve: S. 120 x 40 cm / L 145 x 40 cm Arm sleeve: S. 70 x 25 cm / L 90 x 25 cm Leg sleeve: S. 90 x 30 cm / L 110 x 30 cm, XL 110 x 35 (double zippers) Leg sleeve extension piece 10 cm width	Similar
12	Sleeve chamber	4 chambers	4 chambers	
13	Compression Cycle	85s~133s, ±Is	Leg Sleeves: 11 Seconds Compression Foot Cuffs: 5 Seconds Compression Decompression time based upon Vascular Refill Detection measurement	Similar
14	Patient contact materials/part	TPU material	TPU material	Same

7.5 Equivalence Conclusion

The above information compares the technical information between subject device and the equivalent product which was CE-marked. Comparisons were made between the proposed product and its equivalent device. In conclusion, these two devices are substantial equivalent at technical, biological and clinical characteristics. Though there are some difference, through gap analysis, there is be no clinically significant difference in the safety and clinical performance of the device. The few differences do not affect the safety and effectiveness of the devices under evaluation. It proves the substantial equivalence.

7.5.1 Summary information from clinical-related literatures of similar devices

Literature no.	Intended use	Subjects of laper	Testing device	Specification of paper	Method of paper	The subject of clinical trial	Key words
Literature 1	Lymphedema	13 articles	nfennittent Pneumatic Compression	10-125mmHg	Review	Adults	There is no standard consensus for the frequency of IPC treatments. Attention to patient adherence, identification of barriers to IPC treatment and willingness to tailor treatment prescription should be investigated as mechanisms to ensure optimal IPC use. IPC use undoubtedly contributes to volumetric reduction of lymphedema.
Literature 2	Venous thromboenibolisin (VTE)	379	jitermittent Pneumatic Compression (Kendall SCD EXPRESS, Covidien, Mansfield, MA, USA)	Leg Sleeves: 45 mmHg Foot Sleeves: 130 nimHg	Original article	Adults, age: 52.9± 14.3 in Seoul national university hospital	The results of this study suggest that IPC might be an efiective and safe method for the prevention of postoperative VTE.
Literature 3	Deep vein thrombosis (DVT)	120	ntennittent Pneumatic Compression VenaFlow® Elite System (DJQLLC, Vista, *CA,* USA))	45iumHg	Original article	Adults>45 years in Shanghai Tenth People's Hospital	Compared with the use of rivaroxaban, alone, IPC devices combined with anticoagulants can. significantly reduce the incidence rate of distal DVT and inteimuscular DVT in the early postoperative period after TKA.

Literature 4	Venous thromboembolism (VTE)	7 articles 1001 patients	[ntermittent Pneumatic Compression.	N/A	Review	adults	In. summary, IPC is effective in reducing DVT complications in gynecologic surgery. IPC is neither superior nor inferior to pharmacological thromboprophylaxis. However, whether combination ofIPC and chemoprophylaxis is more effective than IPC or chemoprophylaxis alone remains uriknown in this patient population.
Literatuie 5	Venous thromboembolism (VTE)	741	[ntermittent pneumatic compression ((Kendall Express 9525 SCD: Covidien, Dublin, [reland))	Leg Sleeves: 45 mmHg Foot Sleeves; 130 mmHg	Original Article	Adults (16-89 years) in Korea	This study investigated the effectiveness ofIPC device. We evaluated incidences of deep vein thrombosis (DVT) and pulmonary embolism (PE) in total hip arthroplasty <THA) patients after use of IPC device, and compared with historical incidences f̄r̄. om our institution. It turns out that 1he IPC is a safe and efiective prophylaxis of VTE after primary THA in Korea.
Literature 6	Edema	116	[ntermittent pneumatic compression CKendall 7325 Response SCD pump)	50-72 mmHg	Original Article	Adults	The benefits of the by-pass procedure in. patients with leg ischemia can be significantly reduced, by postoperative edema. Among patients with postoperative leg edema, local tissue blood pei&sion can be improved by itie use ofIPC, which, can result in decreased local leg swelling, as well as improved skin blood perfiision and.TcpO2.

Literatuie 7	Venous fhrombo embolism (VTE)	N/A	ntermittent pneumatic compression	/	Review	AcinIN	IPCDs are appropriate for VTE thromboprophylaxis when used in accordance with current clinical guidelines. The current evidence base to guide selection of a specific device oi type of device is limited. When choos 嗨 a specific IPCD, focusing on device flexibility, acceptability by nursing staff and patients, and the most frequently studied devices, as well as on. cost, can help direct selection of appropriate IPCDs. Comparative effectiveness studies are urgently needed to address current gaps in evidence.
Literature 8	Phlebolymphedem a	81	:ntermittent pneumatic compression 12-chamber apparatus -,ymphatron DL1200 Technomex. LLC, Gliwice,niUpper Silesia, Poland))	60-120mmHg	Original Article	Adults 42-63 years	The IPC with the pressure of 120 mmHg inside the chambers effectively helps to reduce a phlebolymphedema. Furthermore, it appears that the treatments with a pressure of 60 mmHg are inefiective and their application becomes useless only in the antiedematous therapy.

Literature 9	Lymphedema	18	ntermittent pneumatic compiession Biocompression Moonachie, NJ) pneumatic compression)	50-125 mmHg	Original Article	Adults 28-62 years	IPC takes over the permanently missing function of the obliterated lymphatics by squeezing edema tissue fluid, to the regions with normal lymphatic drainage. The limb circumference is decreased or at least does not fiirther increase, elasticity of tissue is increased and maintained. No complications in limb tissues were observed. The long-term, high pressure IPC, long inflation timed therapy can be safely be recommended to patients with lower lnnb lymphedema.
Liteiature 10	Lymphedema	15	ntermittent pneumatic compiession Biocompression Moonachie, NJ) meumatic compression)	50-120minHg	Original Article	Adults 24-62 years	In summary, a) the TF head pressures were lower than those in inflated chambers, b) inflation time of 5 and 20 sec was not long enough to generate TF head pressures above 30 mmHg? even if the compression piessuies were as high as 120 mmHg, c) the 50 sec timing allowed to reach head pressures above 30 mmHg; however, they remained always lower than in the compression chamber, d) TF head pressures differed at various levels of the limb depending on the soft tissue mass, e) deflation of the inHated whole sleeve for 5 and 20 sec was followed by high end pressures, whereas that of 50 sec brougjit about pressure drop to 0, facilitating refilling with TF of the distal parts of the massaged limb.

Liteiature 11	Chronic Lymphedema	12	Flexitouch® system	30-60mmHg	Original Article	Adults 21 years of age or older	Breast cancer survivors with truncal lymphedema may benefit from using an advanced pneumatic compression devices with truncal treatment as part of their self-care program
Liteiature 12	Lymphedema	5	Flexitouch® system	3QPQmmHg	Original Article	Adults 46-66 years of age	Results, determined after 2 months of treatment, showed reductions in trunk and aim swelliiig, fibrotic tissue softening, pain reduction, and improved range of motion and flexibility. Patients reported that FT was easy and comfortable to use and enhanced inhome compliance. Results suggest that limb and trunk lymphedema can be effectively treated in the home with an advanced programmable pneumatic device with truncal coverage, such as the FT system.

8. Clinical data generated by the manufacturer

7.5.2 Product verification

Serial Number	Title	Purpose is to prove	File number
EN ISO 20417:2021	Medical devices - Information supplied by the manufacturer with medical devices	IFU	
EN ISO 15223 1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	Labeling	
EN SO 14971:2019+A11:2021	Medical devices — Application of risk management to medical devices	Risk management	
EN 60601-1:2006+A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Electrical safety	
EN 60601-1-2:2015+A1:2021	Medical electrical equipment part 1: General requirements for safety 2:Collateral standard: Electromagnetic compatibility -requirements and test	Electromagnetic compatibility	
EN 60601-1 6:2010 +A12015+A2:2021	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	Usability	
EN 62366-1:2015+A1:2020	Medical devices - Application of usability engineering to medical devices	Usability	
ISTA 2A:2011	Packaged-Products weighing 150 lb (68 kg) or Less	Transportation report	

9. Adverse event, and recalls notification

9.1 Detailed Documentation of searches, outputs and selection about US FDA adverse event, and recalls notification

1) MAUDE Database: Manufacturer and User Facility Device Experience (MAUDE) database represents reports of adverse events involving medical devices. MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices. The FDA reviews all medical device reports (MDRs) received. The FDA's analysis of MDRs evaluates the totality of information provided in the initial MDR as well as any MDR supplemental reports subsequently provided. The submission of an MDR itself is not evidence that the device caused or contributed to the adverse outcome or event. For example, in certain MDRs, the text of the report may include the word "death" or a related term. However, the MDR would not, and should not, be classified as death unless the reporter believes the patient's cause of death was or may have been attributed to the device or the device was or may have been a factor in the death.

MAUDE Website: MAUDE - Manu facturer and User Facility Device Experie nee (fda.gov)

2) The Total Product Life Cycle (TPLC) database integrates premarket and postmarket data about medical devices. It includes information pulled from CDRH databases including Premarket Approvals (PMA), Premarket Notifications (510[k]), Adverse Events, and Recalls. Thus, we searched all related adverse events, and recalls in this database. Everyone can search the TPLC database by device name or procode to receive a full report about a particular product line. In its current form, the TPLC database provides data by procode, or generic category of device, and not by individual submission or brand name.

TPLC Website: TPLC - Total Product Life Cycle (fda.gov)

3) This database contains Medical Device Recalls classified since November 2002. Since January 2017, it may also include correction or removal actions initiated by a firm prior to review by the FDA. The status is updated if the FDA identifies a violation and classifies the action as a recall and again when the recall is terminated. FDA recall classification may occur after the firm recalling the medical device product conducts and communicates with its customers about the recall. Therefore, the recall information posting date ("create date") indicates the date FDA classified the recall, it does not necessarily mean that the recall is new.

Medical Device Recalls Website: Medical Device Recalls (fda.gov)

9.2 Detailed Documentation of searches, outputs and selection about US FDA adverse event

MAUDE Database

No.	Device Problems	MDRs with this Device Problem	Risk Analysis
1	No	No	No

9.3 Detailed Documentation of searches, outputs and selection about US FDA recalls information

For details of recalls information, we utilize medical device recall database to reach out. And the results indicate no recall information.

10. Conformity assessment with identified GSPR requirements

Conformity assessment with requirement on safety and performance (GSPR 1) The device achieved the performances intended by the manufacturer include technical performance and clinical performance and safety. The ability of device to achieve its intended purpose as claimed by the manufacturer is demonstrated. And the medical effects on humans as well as the clinical benefit on patients are also analyzed.

Conformity assessment with requirement on acceptability of undesirable sideeffects (GSPR 8) After double check, we find that MEDDEV 2.7-1 rev. 4, MDD, MDR do not clearly specify the difference between "side effects" and "complications", but usually describe with the frequent term "side effects or complications". Therefore, we believe "side effects" and "complications" share same meaning. Since there are no side effects. Therefore, this device shall conform to safety requirements from qualitative and quantitative aspects as specified in applicable standards. All risks are identified and summarized in risk management report.
As shown in the Risk Management Report, the residual risks are acceptable. It is confirmed that the device achieves the performances intended by the manufacturer, including all claims made by the manufacturer. So it is not necessary to collect relevant clinical problem data. The relevant risk analysis had been implemented in the risk management report.

11. Section E: Clinical investigations and related documentation

No investigation was conducted.

Rationale why clinical investigation is unnecessary

According to the MDR Annex Ⅳ, this device is falling within Class IIa device. Long-term safety and clinical performance are already known from previous use of the device and post-market surveillance activities provide sufficient data to address the risks.

12. Conclusion

From above-mentioned analysis, relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device are sufficient.

Moreover, after consideration of currently available alternative treatment options for that purpose, this evaluation is demonstrated that the device subject to clinical evaluation for the intended purpose is equivalent to the device to which the data relate and the data adequately demonstrate compliance with the relevant general safety and performance requirements.

The clinical evaluation is actively updated:

1) Immediately when the manufacturer receives new information from PMS that has the potential to change the current evaluation;
2) Every two years if no information received from item 1)