CLINICAL EVALUATION REPORT

临床评估报告

Product: COOLING GEL SHEET

产品：冷贴

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1. General details 总述

State the proprietary name of the device and any code names assigned during device development. Identify the manufacturer(s) of the device.
描述器械的商品名，以及在器械研发过程中使用的任何编码。识别器械的生产商。

本器械商品名：冷贴
Name of the device: Cooling Gel Sheet

生产厂商：佛山拜澳生物科技有限公司
Manufacturer: Foshan Biours Biosciences Co., Ltd.

Description of the device and its intended application 器械描述和预期用途
Provide a concise physical description of the device, cross-referencing to relevant sections of the manufacturer's technical information as appropriate. The description should cover information such as: materials, including whether it incorporates a medicinal substance (already on the market or new), tissues, or blood products; the device components, including software and accessories; mechanical characteristics; and others, such as sterile vs. non-sterile, radioactivity etc.
State the intended application of the device, single use/reusable; invasive/noninvasive; implantable; duration of use or contact with the body; organs, tissues or body fluids contacted by the device.
Describe how the device achieves its intended purpose.
对该器械进行简明的物理描述，适当参照生产商技术信息的相关章节。此描述应包含的信息，
如：材料，包括是否含药（已经上市的或全新的）、组织或血液产品；
器械组成，包括软件和附件；
机械特征；和 其他，如灭菌，非灭菌，放射能等等。
描述器械的预期用途，一次性使用/多次使用；侵入/非侵入；可植入；使用持续时间或与人体接触；器械接触的器官，组织或体液。
描述器械如何达到它的预期用途。

由高岭土、聚丙烯酸钠、二羟基氨基乙酸铝、乙二胺四乙酸二钠、蓝色/绿色/红色/橙色色素、甘油、纯化水、外套和固定器具组成。通过水的蒸发吸热，带走人体发烧时产生的热量，从而达到降温退热的效果。不含有发挥药理学、免疫学或者代谢作用的成分，不包含附录《部分第一类医疗器械产品禁止添加成分名录》所列成分。非无菌产品。
Composed of kaolin, sodium polyacrylate, aluminum dihydroxyaminoacetate, disodium ethylenediaminetetraacetate, blue/green/red/orange pigments, glycerin, purified water, jacket and fixture. Through the evaporation of water, it absorbs heat and takes away the heat generated when the human body has a fever, thereby achieving the effect of cooling and relieving fever.Does not contain ingredients that exert pharmacological, immunological or metabolic effects, and does not contain ingredients listed in the appendix "List of Prohibited Ingredients for Certain Class I Medical Device Products".Non-sterile products.

2. Intended therapeutic and/or diagnostic indications and claims 预期治疗和/或诊断说明和要求

State the medical conditions to be treated, including target treatment group and diseases. Outline any specific safety or performance claims made for the device.
描述使用时的医学条件，包括目标治疗群体和疾病。概述器械的任何特殊安全或性能要求。

用于发热患者的局部降温。仅用于体表完整皮肤。该器械的无特殊安全或性能要求。
For local cooling of patients with fever. For use on intact skin only. There are no special safety or performance requirements for this device.

3. Context of the evaluation and choice of clinical data types 评估背景和临床数据类型的选择

Outline the developmental context for the device. The information should include whether the device is based on a new technology, a new clinical application of an existing technology, or the result of incremental change of an existing technology. The amount of information will differ according to the history of the technology. Where a completely new technology has been developed, this section would need to give an overview of the developmental process and the points in the development cycle at which clinical data have been generated. For long-standing technology, a shorter description of the history of the technology (with appropriate references) could be used. Clearly state if the clinical data used in the evaluation are for an equivalent device. Identify the equivalent device(s) and provide a justification of the equivalency, cross-referenced to the relevant non-clinical documentation that supports the claim.
概述器械的发展历史。内容应包括器械是否基于新技术，是否基于现有技术的新临床应用，或者是现有技术增量变化的结果。根据该技术的历史，信息量将有所不同。如果是一项全新技术发展起来，本章须概述发展过程和发展周期中产生临床数据的节点。如果是常规技术，须简短描述该技术的历史（须适当引用）。明确指出，评估中使用的临床数据是否来自等同器械。识别等同器械，并给出等同的理由，参照相关非临床文献，以支撑观点。

该器械技术源于日本巴布剂技术，在日本有悠久的应用历史。为常规技术。本器械评估中使用的临床数据来自等同器械。
This device technology originated from Japanese cataplasm technology and has a long history of application in Japan. For conventional technology. The clinical data used in the evaluation of this device were obtained from equivalent devices.

State the Essential Requirements relevant to the device in question, in particular, any special design features that pose special performance or safety concerns (e.g. presence of medicinal, human or animal components) that were identified in the device risk management documentation and that required assessment from a clinical perspective.
陈述有关讨论的器械的基本要求，特别是，任何导致特殊性能或安全特性（如药，人体或动物组织的使用）的特殊设计已经在器械风险管理文件中被识别过，并从临床的角度进行了必要的评估。

医疗器械的基本要求是安全有效. The basic requirement for medical devices is safety and effectiveness

冷贴在安全方面从临床的角度已进行了必要的评估，直贴式接触人体皮肤，在风险管理文件中已被识别，并按照设计要求对热贴产品进行了检验，均为合格（见相关检验报告）。
Cooling Gel Sheets have undergone necessary safety assessments from a clinical perspective. They are directly attached to human skin and have been identified in risk management documents. Cooling Gel Sheet products have been inspected in accordance with design requirements and are all qualified. (See test report)

Outline how these considerations were used to choose the types of clinical data used for the evaluation. Where published scientific literature has been used, provide a brief outline of the searching/retrieval process, cross-referenced to the literature search protocol and reports.
概述这些需要考虑的因素如何用来选择评估中用到的临床数据的类型。如果引用已出版的科学文献，请简要描述检索/回溯过程，参照文献检索草案和报告。

依冷贴的特性需要考虑的因素有使用者的年龄、身体状况。年龄因素：婴幼儿及儿童应在成人监护下使用。身体状况因素：不能贴敷于伤口、粘膜、湿疹等皮肤损伤处。在临床评估中应剔除上述因素的临床数据。
Factors that need to be considered depending on the characteristics of the cooling gel sheets include the age and physical condition of the user. Age factor: Infants and children should be used under adult supervision. Physical condition factors: Do not apply it to wounds, mucous membranes, eczema and other skin injuries. Clinical data that exclude the above factors should be excluded from clinical evaluation.

4. Summary of the clinical data and appraisal 总结临床数据和评价

Provide a tabulation of the clinical data used in the evaluation, categorized according to whether the data address the performance or the safety of the device in question. (Note: many individual data sets will address both safety and performance.) Within each category, order the data according to the importance of their contribution to establishing the safety and performance of the device and in relation to any specific claims about performance or safety. Additionally, provide a brief outline of the data appraisal methods used in the evaluation, including any weighting criteria, and a summary of the key results.
提供一张评估中用到的临床数据的表格，按照数据是否关系到讨论的器械的性能或安全来分类。（注：许多单独的数据与安全、性能都相关。）每个类别中，数据的排列依据它们对于该器械安全和性能的重要性，以及与性能和安全有关的任何特别要求的相关方面。此外，简要描述评估中使用的数据评价方法，包括任何权重标准，和重要结论的总结。

表一：冷贴（cooling gel sheet）临床评估数据 chart (1) evaluation of clinical data for cooling gel sheet

指标类别 items	重要性排序 importance sort	标准要求 Standard required	近一年来数据统计均值 Average statistic close to a year
安全指标 safety	皮肤刺激性 Skin irritation	无或极轻微反应 Negative or very slight reaction	极轻微刺激 very slight reaction
	迟发型过敏反应 Formed tardive anaphylaxis	无 Negative	无 Negative
性能指标 characteristic	初黏力 Initial adhesion	应能黏附 3 号钢球 Should be able to adhere to No. 3 steel balls	符合 pass
	持黏力 Stickiness	下滑位移量应不超过 1cm The sliding displacement should not exceed 1cm	符合 pass
	耐热性 Heat resistance	在 42℃±2℃下保持 30 分钟后取出，凝胶应不流淌。 Take it out after keeping it at 42℃±2℃ for 30 minutes. The gel should not flow.	符合 Pass
	耐寒性 Cold resistance	在-1℃±1℃下保持 30 分钟后取出，凝胶应不结冰。 Take it out after keeping it at -1℃±1℃ for 30 minutes. The gel should not freeze.	符合 pass
	降温性能 Cooling performance	4h 内降温不小于 1℃。 The temperature drop should not be less than 1℃ within 4 hours.	符合 Pass
	包装密封性 Packing tightness	包装应密封完好，无连续气泡溢出，无试验用水渗入。 The packaging should be well sealed, with no continuous air bubbles leaking out, and no test water infiltrating.	符合 pass

通过对评估数据的统计分析，所有数据均在标准要求范围内。
After statistical analysis for evaluation data, all data are in scope of standard requirements.

冷贴临床评估数据表
Chart of the cooling patches clinical evaluation data

Include full citations for literature-based data and the titles and investigation codes (if relevant) of any clinical investigation reports.
包括任何临床研究报告的基于文献的数据，题目和研究编码（如果相关）的完整引用信息。

Cross-reference the entry for each piece of data to its location in the manufacturer's technical documentation.
每条数据的记录与其在生产商技术文档中的位置应相互对应。

见生产记录和检验记录。See record of production and inspection record.

5. Data Analysis 数据分析

5.1. Performance 性能

Provide a description of the analysis used to assess performance.
描述用于性能评估的分析方法。

降温性能：取样品连同完好包装于 23℃±1℃、相对湿度 40%～70%条件下放置 8h 以上预处理。在温度保持为 40℃±1℃、相对湿度为 50%±10%的恒温恒湿箱中，安装四个热电偶温度探头，一个探头用于测量恒温恒湿箱中空间的实时温度（以下简称热电偶 A），另三个热电偶探头分别被包裹产品，用于测量样品在模拟使用状态下的实时温度（以下简称热电偶 B、热电偶 C、热电偶 D）。当热电偶 A 测得恒温恒湿箱中空间的实时温度到 40℃时，分别取预处理后的产品揭除防粘层，分别使凝胶面紧紧包裹住恒温恒湿箱中的热电偶 B、热电偶 C、热电偶 D，开始计时，分别在 10min、20min、30min、40min、50min、60min、90min、120min、150min、180min、210min、240min 时读取由热电偶 A 所测得的温度为 Tai，由热电偶 B、热电偶 C、热电偶 D 分别所测得的温度分别为 Tbi、Tci、Tdi。

Cooling performance: Take the sample together with the intact packaging and place it at 23℃±1℃ and relative humidity of 40% to 70% for more than 8 hours for pretreatment. In a constant temperature and humidity box with a temperature maintained at 40 ℃ ±1 ℃ and a relative humidity of 50% ±10%, four thermocouple temperature probes are installed. One probe is used to measure the real-time temperature of the space in the constant temperature and humidity box (hereinafter referred to as Thermocouple A), and the other three thermocouple probes are wrapped in the product and used to measure the real-time temperature of the sample under simulated use (hereinafter referred to as

Thermocouple B, Thermocouple C, Thermocouple D). When thermocouple A measures the real-time temperature of the space in the constant temperature and humidity box to 40 ℃, take the pretreated products and remove the anti-adhesive layer, and make the gel surface tightly wrap around the thermocouple in the constant temperature and humidity box. B. Thermocouple C, Thermocouple D, start timing, and read the temperature measured by thermocouple A at 10min, 20min, 30min, 40min, 50min, 60min, 90min, 120min, 150min, 180min, 210min, and 240min respectively. is Tai, the temperatures measured by thermocouple B, thermocouple C, and thermocouple D are Tbi, Tci, and Tdi respectively.

Identify the datasets that are considered to be the most important in contributing to the demonstration of the overall performance of the device and, where useful, particular performance characteristics. Outline why they are considered to be pivotal and how they demonstrate the performance of the device collectively (e.g. consistency of results, statistical significance, clinical significance of effects).
识别那些被认为是论证了器械总体性能和特殊性能特点的最重要的数据。概述这些数据为何被认为是关键数据，它们如何共同论证了器械的性能 (比如结论的连贯性，统计的显著性，疗效的临床重要性)。

本器械总体性能和特殊性特点的数据为降温性能。冷贴的最主要功能为降温。
Data on the overall performance and specific characteristics of this device are cooling properties. The main function of cooling gel sheet is to cool down.

5.2. Safety 安全

Describe the total experience with the device, including numbers and characteristics of patients exposed to the device; and duration of follow-up of device recipients.
描述器械的全部使用经验，包括使用此器械的患者的数量和特点；以及跟踪器械使用情况的持续时间。

本器械全部使用经验包括如下方面：The total experiences with the device are shown below:
使用方法：Usage:

沿缺口撕开包装袋，取出贴剂，揭开保护膜，将凝胶面直接敷贴于需要降温且清洁好的皮肤部位。可根据需要适当裁剪后，再行使用。
Tear open the packaging bag along the gap, take out the patch, uncover the protective film, and apply the gel surface directly to the skin area that needs cooling and cleansing. It can be cut appropriately as needed before use.

注意事项：Attention:
1.不能贴敷于伤口、粘膜、湿疹等皮肤损伤处。
2.一次性外用品，请勿重复使用。
3.使用前请清洁使用部位并保持干爽，以免汗水、头发等影响产品粘性。

4.使用中若出现局部皮肤不适，立即停止使用，严重者请医师诊治。
5.婴幼儿及儿童应在成人监护下使用，防止误用误食。
6.本品用于辅助降温，发热持续不退者，应接受医师诊治。
1. Do not apply it to wounds, mucous membranes, eczema and other skin injuries.
2. Disposable external products, please do not reuse them.
3. Please clean the application area and keep it dry before use to prevent sweat, hair, etc. from affecting the viscosity of the product.
4. If local skin discomfort occurs during use, stop using it immediately. In severe cases, please consult a physician.
5. Infants and children should use it under adult supervision to prevent misuse and ingestion.
6. This product is used to assist cooling. If the fever persists, you should receive medical treatment.

Provide a summary of device-related adverse events, paying particular attention to serious adverse events.
总结与器械有关的不良事件，特别注意严重不良事件。

未收集到本器械有关的不良事件。
No device-related adverse events get involved.

Provide specific comment on whether the safety characteristics and intended purpose of the device requires training of the end-user.
要特别讨论，是否会因为器械的安全特性和预期用途，须对最终用户进行培训。

本器械要求用户按说明书使用，无需对最终用户进行培训。
The device requires end-users to operate by instruction book, no need training.

5.3. Product Literature and Instructions for Use 产品文献和使用说明

State whether the manufacturer's proposed product literature and Instructions for Use are consistent with the clinical data and cover all the hazards and other clinically relevant information that may impact on the use of the device.
声明生产商提到的产品文献和使用说明书是否与临床数据一致，并包含所有风险和其他可能影响到器械使用的相关的临床信息。

声明：上述提到的产品文献和使用说明书与临床数据一致，并包含所有风险和其他可能影响到器械使用的相关的临床信息。
Statement: the product literature and instructions for use of the product mentioned above are consistent with the clinical data and cover all the hazards and other clinically relevant information that may impact on the use of the device.

6. Conclusions 结论

Outline clearly the conclusions reached about the safety and performance of the device from the evaluation, with respect to the intended use of the device. State whether the risks identified in the risk management documentation have been addressed by the clinical data.
For each proposed clinical indication state whether:
the clinical evidence demonstrates conformity with relevant Essential Requirements;
the performance and safety of the device as claimed have been established;
and the risks associated with the use of the device are acceptable when weighed against the benefits to the patient.
简明概述从评估延伸到器械安全和性能的结论，同时考虑器械的预期用途。描述临床数据是否涉及了从风险管理文件中识别出的风险。
对于每个提到的临床说明，须声明：
临床证据是否论证了符合相关基本要求；
如同所声称的，是否已确定器械的性能和安全；以及
与患者的受益相权衡，与器械使用相关的风险是否是可接受的。

本次评估的临床数据涉及了从风险管理文件中识别出的风险，通过临床评估可以得出结论，即使用者在使用器械时，在得到预期用途的同时，安全性和相关风险是可以接受的。

The evaluation of the clinical data involves risks identified in risk management documentation. The conclusion is when the end-user is operating the device, safety and risks associated with the use of the device are acceptable, with respect to the intended use of the device.