April 2, 2026

Medical Brands Laboratories B.V.
Pieternella Bouter
Chief Commercial Officer (CCO)
Weesperstraat 114
Diemen, 1112AP
Netherlands

Re: K252198
Trade/Device Name: Advanced Cryo Skin Tag Remover (Advanced Skin Tag Remover)
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: June 19, 2025
Received: July 14, 2025

Dear Pieternella Bouter:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JAMES H. JANG -S
Digitally signed by JAMES H. JANG -S
Date: 2026.04.02 16:15:34 -04'00'

James Jang, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252198

Please provide the device trade name(s).

Advanced Cryo Skin Tag Remover (Advanced Skin Tag Remover)

Please provide your Indications for Use below.

Advanced Cryo Skin Tag Remover is intended to allow users direct access to a safe and effective method for the removal of skin tags. The device is indicated for over-the-counter (OTC) treatment in the removal of skin tags in adults aged 22 years and older.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510 (k) number K252198
(As required by 21 CFR 807.92)_v5.0

807.92(a)(1)

Submission Sponsor:	Medical Brands Laboratories B.V. Weesperstraat 114, 1112 AP, Diemen, The Netherlands +31 (0)20 345 53 30 Drs. P. Bouter
Date Prepared:	March 30, 2026

807.92(a)(2)

Device Identification:

Device Name:	Advanced Cryo Skin Tag Remover
Trade/Proprietary Name	Advanced Skin Tag Remover (on the labelling)
Common/Usual Name:	Cryosurgical unit and accessories
510 (k) number:	K252198
Classification Name:	General & Plastic Surgery
Regulation Number:	21 CFR 878.4350
Product Code:	GEH, Unit, Cryosurgical, Accessories
Class:	II
Classification Panel:	General and Plastic Surgery (878.4350 - Cryosurgical unit and accessories)

510 (k) number K252198
(As required by 21 CFR 807.92)_v5.0

807.92(a)(3)

Predicate device:

Device Name:	Freeze 'n Clear Skin Clinic for Warts and Skin Tags
Proprietary Name:	Skin Clinic Freeze 'n Clear Skin Tag Remover Dr. Scholl's Freeze Away® Skin Tag Remover
510 (k) number:	K211099
Manufacturer:	CryoConcepts LP
Regulation Number	21 CFR 878.4350
Product Code	GEH, Unit, Cryosurgical, Accessories
Class:	II
Classification Panel:	General and Plastic Surgery (878.4350 - Cryosurgical unit and accessories)

807.92(a)(4)

Description of the Subject Device

The Advanced Cryo Skin Tag Remover is identical in design, materials, and performance characteristics to the previously cleared Advanced Cryo Wart Remover (K242288), with no changes to the device design, materials of construction, operating principles, or performance. Accordingly, all previously submitted supporting information and test data, including biocompatibility, remain applicable to the subject device. The only modifications are (1) the product name, updated from Advanced Cryo Wart Remover to Advanced Cryo Skin Tag Remover, and (2) the indication for use, which has been changed to the over-the-counter (OTC) treatment in the removal of skin tags in adults aged 22 years and older.

The Advanced Cryo Skin Tag Remover is an over-the-counter (OTC) cryotherapy device designed for the treatment of facilitating the removal of skin tags utilizing extreme cold. The device includes:

- A 15 mL / 0.51 oz pressurized aerosol canister containing a freezing agent (1,1-Difluoroethane, Propane, and Isopentane).
- A metal tip that applies the cryogen directly to the skin lesion
- Optional circular plasters
- Detailed instructions, including illustrated descriptions.

Optional circular plasters are provided if the user needs extra precision and protection. If used, the plaster is to be positioned around the skin tag, ensuring the opening aligns precisely over the target area. To

activate the product, the user must, while holding the device facing downward, press the side buttons firmly five times in a row, wait 2 seconds, and then apply the cold metal tip for 40 seconds on the skin tag.

The device is non-sterile, reusable, and intended for home use by laypersons. No assembly, special training, or sterilization is required for operation.

880.5240

Accessories Justification

Accessory: Optional circular adhesive plaster with central hole
Contact type: External communicating, intact skin contact
Duration of use: ≤24 hours (short-term)
Regulatory Classification: Class I, 510(k)-exempt under 21 CFR 880.5240, Product Code FRO

The plaster provided with the Advanced Cryo Skin Tag Remover is classified as a non-critical accessory and its use is optional. This plaster is composed of:

Backing: Aluminium Foil
Adhesive: Acrylic Pressure Sensitive Adhesive
Pad structure: Viscose Polyester

These materials are standard in over-the-counter Class I adhesive dressings regulated under 21 CFR 880.5240, Product Code FRO, which are 510(k)-exempt when not bearing therapeutic or drug-delivery claims. The single-use plaster has direct contact with intact skin, is non-sterile, and intended for <24-hour application.

807.92(a)(5)

Indication for use and Intended Users of Subject Device

The Advanced Cryo Skin Tag Remover is intended to allow users direct access to a safe and effective method for the removal of skin tags. It is indicated for over-the-counter (OTC) treatment in the removal of skin tags in adults aged 22 years and older.

Indication for use Comparison

The subject device has the same indications for use as the predicate device (the Skin Clinic Freeze 'n Clear Skin Tag Remover).

510 (k) number K252198
(As required by 21 CFR 807.92)_v5.0

807.92(a)(6)

Technological Comparison

Table: Comparison of Characteristics

	Subject Device	**Predicate Device**	**Differences**
Trade Name /Device Name	Advanced Cryo Skin Tag Remover	Freeze'n Clear Skin Clinic Warts & Tags	Not applicable
Other Names	Advanced Skin Tag Remover	Skin Clinic Freeze 'n Clear Skin Tag Remover Dr. Scholl's Freeze Away Skin Tag Remover	Not applicable
510(k) Number	K252198	K211099	Not applicable
Original Applicant	Medical Brands Laboratories B.V.	CryoConcepts LP	Not applicable
Regulatory Classification			
Regulatory Class	Class II	Class II	None
Name of Generic Device Type	Cryogenic skin tag remover	Cryogenic skin tag remover	None
Regulation	21 CFR § 878.4350	21 CFR § 878.4350	None
Product Code	GEH	GEH	None
Device Description – Substantial Equivalence Comparators			
Intended Use	To allow users direct access (OTC) to a safe and effective method for the removal of skin tags.	The Freeze 'n Clear Skin Clinic for Warts and Skin Tags product is intended for consumer use for the treatment of common warts, plantar warts and skin tags. *Marketed product Skin Clinic Freeze 'n Clear Skin Tag Remover states: Skin Clinic Freeze 'n Clear Skin Tag Remover is	The predicate has an additional intended use for wart removal (though the marketed product - Skin Clinic Freeze 'n Clear Skin Tag Remover - has only the skin tag indication).

		intended for the removal of skin tags.	
OTC or Rx	OTC	OTC	None
Indication for Use	The OTC treatment for the removal of skin tags in adults aged 22 years and older.	The OTC treatment of common warts, plantar warts, and skin tags.	The predicate has an additional intended use for wart removal (though the marketed product Skin Clinic Freeze 'n Clear Skin Tag Remover has only the skin tag indication). Age on the outer box states "Safe for 21 years and up"
Technological Characteristics	Pressurized gas canister that applies extreme cold to target tissue; Cryogen is used to cool the metal tip, which is applied to the skin tag, causing rapid cooling.	Pressurized gas canister that applies extreme cold to target tissue; Cryogen is used to cool the foam tip, which is applied to the wart or skin tag, causing rapid cooling.	The subject device has a metal tip while the predicate device has a foam tip.
Device Description - Design Features			
Energy	Thermal (removal of heat from treated skin)	Thermal (removal of heat from treated skin)	None
Package Contents	A pressurized canister containing cryogen with a metal tip fixed to applicator (form of a pen), protective plasters, IFU leaflet	A pressurized canister containing cryogen, precision foam-tip applicators, tweezers, IFU leaflet	The subject device is a pen-style applicator with a fixed metal tip and includes optional protective plasters intended to help isolate the skin tag from adjacent healthy skin during application. The predicate device uses replaceable foam-tip applicators that are attached prior to activation and includes tweezers intended to help isolate the skin tag for treatment.
Mode of Action	Destruction of target	Destruction of target	None

	skin cells by freezing	skin cells by freezing	
Directions for use	Press the side buttons firmly five times in a row, while holding the device facing downward; wait 2 seconds; apply cold tip directly onto the skin tag	Attach applicator tip to handle; press actuator down for 3-5 seconds; wait 15 seconds; pull skin tag away from the body with supplied tweezers and apply applicator tip to skin tag base continuously for 40 seconds	The subject device does not need assembly, has a quicker, user-friendly activation, and shorter waiting period before application.
Duration of treatments for Skin Tags	40 seconds	40 seconds	None
Cryogen	1,1-Difluoroethane, propane, and isopentane	Dimethyl ether, propane, and isobutane	Both devices use a cryogen/propellant blend to generate cooling via rapid evaporation/expansion. The subject device contains 1,1-difluoroethane, a fluorinated hydrocarbon propellant. The predicate device contains dimethyl ether, an oxygenated, solvent-like propellant. Additionally, the subject device includes isopentane (a heavier, less volatile hydrocarbon) while the predicate device includes isobutane (a more volatile hydrocarbon). Differences in constituent volatility can influence vapor pressure, flow characteristics, and the manner in which cooling is delivered to the applicator tip, however both devices achieve their intended effect through

			controlled localized cooling.
Applicator & Tip Diameter	Metal (nickel-chrome) tip Tip diameter = 4.9 mm.	Foam Applicator Tip Diameter ≈ 2.0 – 5.0 mm	Serves the same functional purpose as a delivery interface for a cryogen-based cooling. The subject's fixed metal tip diameter is within the range of the predicate's compressible foam tip diameter (dependent on user applied pressure)
Lowest Freezing Temperature measured	-57°C	-57°C	None
Maximum allowed treatment cycles	Four treatment cycles. Each treatment should be followed by a 2 week interval period.	If the skin tag has not fallen off in 2 weeks, can treat the skin tag again up to 4 treatment cycles.	None
Sterile Device	No	No	None
Leaflet included	Yes	Yes	None
Use environment	Home	Home	None
Anatomical site of use	Skin	Skin	None
Electricity or radiation used	No	No	None

807.92(b)(7)

Non-clinical Performance Data

To demonstrate safety and effectiveness of the Advanced Cryo Skin Tag Remover and to show substantial equivalence to the predicate device, the following non-clinical tests were performed.

Biocompatibility Testing per ISO 10993-1 – Supports biocompatibility of the device.

- ISO 10993-5 (cytotoxicity)
- ISO 10993-10 (irritation)
- ISO 10993-10 (sensitization)

- ISO 10993-17 (toxicological risk assessment (TRA)
- ISO 10993-18 (chemical characterization)

- The overall biological safety of the device for its intended use, duration of exposure and target population was evaluated. Based on the performed and documented biological safety assessment we confirm that the risk analysis and the risk controls have been completed. The components of the Advanced Cryo Skin Tag Remover have been extensively tested for the potential toxicity and potential risk to human health. It can be concluded that there are no changes in physical-chemical properties and that the formulations are stable.
- No risks relevant to its main components have been identified regarding ADME. Keeping in mind that absorption does not take a role to achieve the primary mode of action. An assessment of risks and benefits regarding biological safety of the subject device has been carried out. Therefore, by using it according to the Instructions for Use, users are exposed to safe daily amounts of components. This conclusion is supported by Post-Market Surveillance (PMS) data.
- The overall biological safety of the device for its intended use, duration of exposure and target population (including special consumer groups within the intended population) was evaluated. An assessment of the data and risks and benefits regarding biological safety of the Advanced Cryo Skin Tag Remover has been carried out after a detailed analysis of relevant published scientific literature. We demonstrate that the information obtained from the literature complies with the applicable test requirements of ISO 10993-1.
- We concluded that the benefits provided by the subject device in its final finished form outweigh its risks over the intended duration and use of the device. Residual risks identified through the biocompatibility analysis and risk management process are disclosed in the Risk Management report. In the Instructions for Use the users are informed about warnings and precautions.

Shelf Life Testing per ASTM D3090-72 – Supports shelf life of 36 months.
Shelf life testing was based on device stability and functionality testing.
Bench Testing – Supports device performance.

- Advanced Cryo Skin Tag Remover was subjected to comparative thermal performance testing over a 60-second interval following standardized activation, that included thermoelectric testing to determine freeze temperature extremes, freeze temperature plateau, and freeze duration. The test provided data on both the temperature profile at the target surface and on the tissue freezing capacity of the device. The results of the tests demonstrated comparable performance to the predicate device. The subject device achieved cryotherapy-level cooling comparable to the predicate, including comparable minimum applicator temperatures and time–temperature profile behavior

- Ex vivo comparative tissue damage testing: A comparative ex vivo study was conducted to characterize tissue effects induced by the subject device (Product A) and predicate device (Product B) using living human skin explants maintained in survival conditions. Following stabilization of skin surface temperature, devices were applied in direct contact for three durations representing short exposure (20 seconds), the IFU-recommended (40 seconds) "realistic-case," and an extended exposure (60 seconds) (n=3 explants per device per timepoint), with histological assessment performed 24 hours post-application. Tissue effects were evaluated by Masson's Trichrome staining, including quantitative measurement of lesion dimensions and calculation of lesion volume. LDH staining was conducted to assess tissue viability.

Across matched tested durations (20s/40s/60s; n=3 per device per timepoint), both devices produced measurable localized cryotherapy-related tissue injury. Lesion depth measurements were of similar magnitude between devices at the IFU-recommended application duration (40 seconds). The predicate generally produced greater lateral lesion extent (width/volume) than the subject under matched conditions. A qualitative observation noted that for the predicate foam tip, liquid condensation extended beyond the primary contact area upon tissue contact, whereas condensation/frost remained localized at the subject metal tip/contact area. Similar lesion depth extent was observed in both devices. Overall, the study supports that the subject device's tissue interaction is comparable to the predicate with respect to lesion depth at the labeled application duration and is not more severe than the predicate under matched application conditions. LDH staining performed on the explants demonstrated findings consistent with those observed with Masson's Trichrome staining, supporting the overall assessment of cryotherapy-induced tissue injury.

- A bench study was conducted to verify that the optional protective plasters that are provided with the Advanced Cryo Skin Tag Remover perform as intended during cryotherapy application, providing protection to surrounding skin without degrading, interfering with cryogen performance, or detaching from skin during use. The results demonstrated secure placement during treatment, no visible material damage from exposure to cold, effective blocking of cryogen spread beyond the treatment zone, easily removable after treatment, and no interaction between cryogen and plaster.

Label and IFU Comprehension Study – Supports device self-selection & labeling comprehension.

- A prospective, open-label usability validation study was conducted to determine whether lay users can correctly interpret and use the information on the outer box packaging label of the Advanced Skin Tag Remover. Feedback from study participants indicated a need for revisions related to language clarity and grammar. These improvements were subsequently implemented in both the outer packaging and the Instructions for Use (IFU) to enhance user comprehension and support safe and effective use.
- To confirm that the proposed labeling is appropriate, a Flesch readability analysis was performed to ensure that the instructions were considered 'readable' to lay consumers. The test generated a Flesch Reading Ease score of 72.58, Flesch-Kincaid Grade Level of 5.1, and a ReadablePro rating of 'A'. According to the report created, the text has a Reach score of 100%, meaning that the text is readable for 100% of the addressable audience, equating to approximately 85% of the general public.

Human Factors Study – Supports safe usability of the device for lay-person use.

- A prospective, open-label usability validation study was conducted to determine whether lay users can correctly interpret and use the information on the outer box packaging label of the Advanced Skin Tag Remover. The study followed IEC 62366-1 and FDA's Human Factors Guidance (2016) and included 20 adult participants (21 years and older), representing diverse educational and geographic backgrounds. The study focused solely on label comprehension without assessing device performance.
- Participants reviewed the product's outer packaging and completed a structured assessment involving skin tag identification, interpretation of contraindications from labeling content, and level of confidence in identifying skin tags. All participants (100%) correctly identified the product's intended use for removal of skin tags. Nineteen participants (95%) accurately identified the image of a skin tag. Eighteen participants (90%) correctly identified the images of non-skin tag lesions as "other skin lesions" and reported them as not suitable for treatment with the product.
- A small subset (≤10%) incorrectly identified the non-skin tag lesions and reported them as treatable

with the product, reinforcing the value of prominent labeling features (such as the red "X" symbols and targeted visual descriptors included in the Advanced Skin Tag Remover Label) in supporting safe independent use.

- All participants (100%) successfully identified two contraindications listed on the packaging label. Eighteen participants (90%) reported feeling "very confident" in identifying skin tags based on the label and two participants (10%) reported feeling "somewhat confident."
- The study confirms that the Advanced Skin Tag Remover outer box packaging label supports safe and effective independent use and validates the visual identification aids on the label are effective in guiding users to make correct treatment decisions, contraindications and warning information is easily located and understood, and potential users have high confidence applying the information to real-world use. No unmitigated critical use errors were observed.

807.92(b)(8)

Clinical Performance Data

No new clinical trials were conducted for the Advanced Skin Tag Remover. A targeted literature review and state-of-the-art assessment were conducted to characterize the use of cryotherapy for skin tags (acrochordons) and to contextualize OTC/home-use cryotherapy devices for the intended adult population. The review prioritized human evidence specific to skin tags treated with cryotherapy and included device-relevant sources such as peer-reviewed clinical studies of OTC skin tag cryogenic devices and publicly available FDA 510(k) summaries for cleared OTC cryotherapy systems with skin tag indications. General cryosurgery references were also used to describe the physical mechanism of action of cryotherapy (controlled localized freezing with freeze–thaw cellular injury and vascular effects) and expected local treatment reactions.

Cryotherapy is a well-established, device-classified treatment that works through a physical mode of action through rapid freezing with cryogens (e.g., dimethyl ether, propane) causing microvascular compromise and targeted tissue necrosis without pharmacological effects. A key peer-reviewed clinical study included a prospective, single-blinded, randomized comparative clinical trial evaluating an OTC/home-use cryogenic devices for treatment of benign skin tags in adults, using repeated treatment cycles with follow-up to assess lesion response and local tolerability. This study supports that OTC cryotherapy can be used to treat benign skin tags and that more than one treatment cycle may be needed depending on lesion characteristics and response (Antunes et al., 2021).

In addition, FDA 510(k) summaries were reviewed to characterize the technological landscape and typical evidence used for OTC cryotherapy devices with skin tag indications. These include the predicate device Freeze'n Clear Skin Clinic for Warts and Skin Tags (K211099) and other cleared OTC systems for skin tags. These publicly available summaries describe comparable intended use paradigms for OTC cryotherapy, including timed direct contact application via an applicator interface and repeat-cycle treatment instructions where applicable, and provide context for the non-clinical performance evidence commonly used for this device type.

807.92(b)(9)

Statement of Substantial Equivalence

Based on the information presented, it is concluded that the Advanced Cryo Skin Tag Remover is substantially equivalent to the Skin Clinic Freeze 'n Clear Skin Tag Remover predicate device.