



BrainCool AB  
% Adam Harris  
Director, Regulatory Affairs  
Target Health LLC  
3800 Paramount Parkway, Suite 100  
Morrisville, North Carolina 27560

Re: DEN210027  
Trade/Device Name: The Cooral System  
Regulation Number: 21 CFR 872.5590  
Regulation Name: Intraoral cooling device  
Regulatory Class: Class II  
Product Code: QUA  
Dated: January 13, 2022  
Received: January 18, 2022

Dear Adam Harris:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the The Cooral System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

The Cooral System is intended to cool the oral mucosa during chemotherapy treatments to reduce the likelihood and severity of chemotherapy induced Oral Mucositis in adult patients.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the The Cooral System, and substantially equivalent devices of this generic type, into Class II under the generic name intraoral cooling device.

FDA identifies this generic type of device as:

**Intraoral cooling device.** An intraoral cooling device is a prescription use device that is intended to cool the mouth for patients to reduce the likelihood of oral mucositis. The device consists of a removable mouthpiece that cools the oral mucosal surfaces.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On

December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On July 2, 2021, FDA received your De Novo requesting classification of the The Cooral System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the The Cooral System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the The Cooral System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

<b>Identified Risks to Health</b>	<b>Mitigation Measures</b>
Thermal tissue damage	Non-clinical performance testing Software verification, validation & hazard analysis Labeling
Electrical shock, or device failure due to electromagnetic interference	Electromagnetic compatibility (EMC) testing Electrical safety testing
Adverse tissue reaction	Biocompatibility evaluation
Discomfort	Labeling
Obstruction or device leakage leading to patient injury	Non-clinical performance testing Labeling

In combination with the general controls of the FD&C Act, the intraoral cooling device is subject to the following special controls:

- (1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and must include:
  - (i) Thermal testing to evaluate cooling consistency and performance; and
  - (ii) Testing of the device to demonstrate material integrity.
- (2) Electromagnetic compatibility (EMC) and electrical safety testing must be performed for any electrical components.
- (3) Software verification, validation, and hazard analysis must be performed for any software components of the device.
- (4) The patient contacting components of the device must be demonstrated to be biocompatible.
- (5) Labeling must include the following:

- (i) A summary of the device specifications, including temperature cooling range and duration of cooling; and
- (ii) Instructions to stop the use of the device if skin irritation or sensitivities develop, or if the device leaks or does not maintain its material integrity.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact [CDRHProductJurisdiction@fda.hhs.gov](mailto:CDRHProductJurisdiction@fda.hhs.gov).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the intraoral cooling device they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 803) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Anita Belani at 301-796-3944.

Sincerely,

for Malvina Eydelman, M.D.

Director

OHT1: Office of Ophthalmic, Anesthesia,  
Respiratory, ENT and Dental Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health