DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA–2026–N–4645]

Medical Devices; Ophthalmic Devices; Classification of the Corneal Storage Medium With Preservatives Including Antifungals

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the corneal storage medium with preservatives including antifungals into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the corneal storage medium with preservatives including antifungals. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective May 6, 2026. The classification was applicable on May 2, 2022.

FOR FURTHER INFORMATION CONTACT: Kesia Alexander, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1406, Silver Spring, MD 20993–0002, 301–796–6482, *Kesia.Alexander@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the corneal storage medium with preservatives including antifungals into class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness of the device. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On November 10, 2020, FDA received AL.CHI.MI.A. S.r.l.'s request for De Novo classification of the Kerasave device. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness of the device, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on May 2, 2022, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 886.4320.[1] We have named the generic type of device ''corneal storage medium with preservatives including antifungals,'' and it is identified as a

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

device that is used to temporarily preserve human cornea tissue between harvesting and implantation.

FDA has identified the risks to health associated with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR CORNEAL STORAGE MEDIUM WITH PRESERVATIVES INCLUDING ANTIFUNGALS

Identified risks to health	Mitigation measures
Infection	Sterilization validation; Non-clinical performance testing; Labeling; and Shelf life testing.
Adverse tissue reaction	Biocompatibility evaluation; and Non-clinical performance testing.
Antimicrobial resistance	Antimicrobial resistance analysis; Non-clinical performance testing; and Labeling.
Worsening prognosis that may need recurring or more invasive surgery due to damage to cornea tissue while in storage.	Non-clinical performance testing; and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for corneal storage media with preservatives including antifungals. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 886

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 886 is amended as follows:

PART 886–OPHTHALMIC DEVICES

■ 1. The authority citation for part 886 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 886.4320 to subpart E to read as follows:

§ 886.4320 Corneal storage medium with preservatives including antifungals.

(a) *Identification.* Corneal storage medium with preservatives including antifungals is a device that is used to temporarily preserve human cornea tissue between harvesting and implantation.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use.

(i) The following performance characteristics of the cornea following storage in the device must be demonstrated:

(A) Endothelial cell density;

(B) Endothelial cell morphology;

(C) Corneal transparency; and

(D) Central corneal thickness.

(ii) Antimicrobial activity of the device must be demonstrated at the initial and maximum labeled storage time.

(iii) Characterization of all preservatives, including antifungals, must include the following:

(A) Characterization of impurities, heavy metal analysis, concentration, and dissolution; and

(B) Chemical activity of all preservatives over the labeled use life of the device.

(2) Performance data must demonstrate the sterility of the device.

(3) The device must be demonstrated to be biocompatible and non-pyrogenic.

(4) Performance data must support the claimed shelf life by demonstrating continued sterility, controlled bioburden, package integrity, and device functionality over the intended shelf life.

(5) The device and each of its components (*e.g.,* antifungal, antibiotic, medium) must be demonstrated to be compatible with their respective commercial container closure system/packaging.

(6) An analysis must be provided that identifies and evaluates any contribution to the development and spread of antimicrobial resistance.

(7) Labeling must include the following instructions:

(i) Rinsing of cornea prior to transplantation; and

(ii) Complete dissolution of all preservatives.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

27 CFR Parts 447, 478, and 479

[ATF No. 2024R–01F]

RIN 1140–AA60

Revising Machine Gun Definition in Response to Supreme Court Decision

AGENCY: Bureau of Alcohol, Tobacco, Firearms, and Explosives, Department of Justice.

ACTION: Final rule.

SUMMARY: The Bureau of Alcohol, Tobacco, Firearms, and Explosives (''ATF'') is amending Department of Justice (''Department'') regulations in response to the Supreme Court's decision in *Garland* v. *Cargill.* The Supreme Court held that ATF exceeded its statutory authority in its December 2018 final rule titled ''Bump-Stock-Type Devices'' by classifying a bump stock as a ''machine gun'' because a semi-automatic rifle equipped with a non-mechanical bump-stock-type device is not a ''machine gun'' under the National Firearms Act. Accordingly, ATF is removing from the three regulatory definitions of ''machine gun'' the two sentences that incorporated bump stocks into those definitions.

DATES: This final rule is effective on May 6, 2026.

FOR FURTHER INFORMATION CONTACT: Office of Regulatory Affairs, by email at *ORA@atf.gov,* by mail at Office of Regulatory Affairs; Enforcement Programs and Services; Bureau of Alcohol, Tobacco, Firearms, and Explosives; 99 New York Ave NE; Washington, DC 20226, or by telephone at 202–648–7070 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

The Attorney General is responsible for enforcing the Gun Control Act (''GCA''), as amended, and the National Firearms Act (''NFA''), as amended.[1] This includes the authority to promulgate regulations necessary to enforce the provisions of the GCA and NFA. *See* 18 U.S.C. 926(a); 26 U.S.C. 7805(a). Congress and the Attorney General have delegated the responsibility for administering and enforcing the GCA and NFA to the Director of ATF (''Director''), subject to the direction of the Attorney General and the Deputy Attorney General. *See* 28 U.S.C. 599A(b)(1), (c)(1); 28 CFR 0.130(a)(1)–(2); Treas. Order No. 221(2)(a), (d); 37 FR 11696–97 (June 10, 1972).[2] Accordingly, the Department and ATF have promulgated regulations implementing both the GCA and the NFA in 27 CFR parts 478, 479.

Following a February 20, 2018, Presidential memorandum,[3] the Department amended ATF regulations by issuing a final rule titled ''Bump-Stock-Type Devices'' (''2018 final rule''), which determined that rifles with an attached bump-stock-type device constituted ''machine guns'' under Federal law.[4] On June 14, 2024, the Supreme Court held that ''a semiautomatic rifle equipped with a [non-mechanical] bump stock is not a 'machinegun' because it cannot fire more than one shot 'by a single function of the trigger.' And, even if it could, it would not do so 'automatically.'''[5] The regulatory definition of ''machine gun'' does not distinguish between non-mechanical and mechanical bump stocks and simply states ''bump-stock-type device.'' ATF will rely on the statutory definition, as well as federal case law, such as *Cargill,* that further defines terms within the ''machine gun'' definition such as ''single function of the trigger'' and ''automatically.''

ATF is now taking steps to conform its regulations with the Supreme Court's decision in *Cargill.* This final rule removes from the Code of Federal Regulations (''CFR'') the revised portions of the regulatory definitions of ''machine gun'' that included bump stocks. Removing these portions of the previous final rule restores the regulatory text for those definitions to what it was prior to the December 2018 rule, with one minor exception.[6]

II. Final Rule

Under the NFA, as amended, and the GCA, as amended, the term ''machinegun'' means ''any weapon which shoots, is designed to shoot, or can be readily restored to shoot, automatically more than one shot, without manual reloading, by a single function of the trigger.'' 26 U.S.C. 5845(b); *see* 18 U.S.C. 921(a)(24) (referencing the NFA definition). The term ''machinegun'' also includes ''the frame or receiver of any such weapon'' or any part or combination of parts designed and intended ''for use in converting a weapon into a machinegun,'' and ''any combination of parts from which a machinegun can be assembled if such parts are in the possession or under the control of a person.'' 26 U.S.C. 5845(b). This statutory definition uses the key terms ''single function of the trigger'' and ''automatically,'' but those terms are not defined in the statutory text. Before the 2018 final rule, the regulations contained definitions for the term ''machine gun'' in 27 CFR 478.11 and 479.11, that mirrored the NFA's statutory definition.

The definition of ''machinegun'' in 27 CFR 447.11, promulgated pursuant to the portion of section 38 of the Arms Export Control Act (''AECA'') (22 U.S.C. 2778) delegated to the Attorney General by section 1(n)(ii) of Executive Order 13637, 78 FR 16129 (Mar. 13, 2013), is similar, but not identical. Before the 2018 final rule, the definition of machine gun in 27 CFR 447.11 provided that a '''machinegun,' 'machine pistol,' 'submachinegun,' or 'automatic rifle' is a firearm originally designed to fire, or capable of being fired fully

[1] Some NFA and GCA provisions still refer to the ''Secretary of the Treasury.'' However, the Homeland Security Act of 2002, Public Law 107–296, 116 Stat. 2135, transferred the functions of ATF from the Department of the Treasury to the Department of Justice, under the general authority of the Attorney General. 26 U.S.C. 7801(a)(2); 28 U.S.C. 599A(c)(1). Thus, for ease of reference, this final rule refers to the Attorney General where relevant.

[2] In Attorney General Order Number 6353–2025, the Attorney General delegated authority to the Director to issue regulations pertaining to matters within ATF's jurisdiction, including under the NFA, GCA, and Title XI of the Organized Crime Control Act. ATF's jurisdiction also includes the Arms Export Control Act and the Contraband Cigarette Trafficking Act.

[3] On February 20, 2018, President Trump issued a memorandum instructing the Attorney General ''to dedicate all available resources to . . . propose for notice and comment a rule banning all devices that turn legal weapons into machineguns.'' Presidential Memorandum (Application of the Definition of Machinegun to ''Bump Fire'' Stocks and Other Similar Devices), 83 FR 7949 (Feb. 20, 2018); U.S. Dep't of Justice, *Attorney General Sessions Announces Regulation Effectively Banning Bump Stocks* (Mar. 23, 2018), *https://www.justice.gov/opa/pr/attorney-general-sessions-announces-regulation-effectively-banning-bump-stocks* [*https://perma.cc/S7DZ-76XD*].

[4] 83 FR 66514 (Dec. 26, 2018); 84 FR 9239 (Mar. 14, 2019) (ratifying final rule).

[5] *Garland* v. *Cargill,* 602 U.S. 406, 415 (2024).

[6] Consistent with the Supreme Court's decision, ATF is not reinserting the sentence segment ''is a firearm originally designed to fire, or capable of being fired fully automatically by a single pull of the trigger'' in the pre-rule definition of ''machinegun'' found in 27 CFR 447.11, nor is it removing the sentence that includes frames and receivers, conversion parts, and combinations of parts in the definition. See discussion below.