212–CB, C–212–CC, C–212–CD, C–212–CE, C–212–CF, and C–212–DF airplanes, as modified by Xtreme.

In lieu of Title 14, Code of Federal Regulations (14 CFR) 25.1353(b)(1) through (4) at amendment 25–123 or § 25.1353(c)(1) through (4) at earlier amendments, each rechargeable lithium battery installation must:

1. Be designed to maintain safe cell temperatures and pressures under all foreseeable operating conditions to prevent fire and explosion.

2. Be designed to prevent the occurrence of self-sustaining, uncontrollable increases in temperature or pressure, and automatically control the charge rate of each cell to protect against adverse operating conditions, such as cell imbalance, back charging, overcharging, and overheating.

3. Not emit explosive or toxic gases, either in normal operation or as a result of its failure, that may accumulate in hazardous quantities within the airplane.

4. Meet the requirements of § 25.863.

5. Not damage surrounding structure or adjacent systems, equipment, or electrical wiring from corrosive fluids or gases that may escape in such a way as to cause a major or more severe failure condition.

6. Have provisions to prevent any hazardous effect on airplane structure or systems caused by the maximum amount of heat it can generate due to any failure of it or its individual cells.

7. Have a failure sensing and warning system to alert the flightcrew if its failure affects safe operation of the airplane.

8. Have a monitoring and warning feature that alerts the flightcrew when its charge state falls below acceptable levels if its function is required for safe operation of the airplane.

9. Have a means to automatically disconnect from its charging source in the event of an over-temperature condition, cell failure or battery failure.

**Note:** A battery system consists of the battery, battery charger and any protective, monitoring and alerting circuitry or hardware inside or outside of the battery. It also includes vents (where necessary) and packaging. For the purpose of this special condition, a battery and the battery system is referred to as a battery.

Issued in Des Moines, Washington, on April 28, 2026.

**Paul R. Siegmund,**

*Deputy Manager, Technical Policy Branch, Policy and Standards Division, Aircraft Certification Service.*

[FR Doc. 2026–08903 Filed 5–5–26; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 27

**[Docket No. FAA–2025–2303; Special Conditions No. 27–059–SC]**

## Special Conditions: Skyryse, Robinson Helicopter Company Model R66 Helicopter; Static Longitudinal Stability

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final special conditions.

**SUMMARY:** These special conditions are issued for the Robinson Helicopter Company (Robinson) Model R66 helicopter. This helicopter, as modified by Skyryse, will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for normal category rotorcraft. This design features a four-axis full authority digital fly-by-wire (FBW) flight control system (FCS), which provides aircraft control through pilot input or coupled autopilot modes. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

**DATES:** Effective June 5, 2026.

**FOR FURTHER INFORMATION CONTACT:** Mitch Soth, Product Policy Management, AIR–62B, Technical Policy Branch, Policy and Standards Division, Aircraft Certification Service, Federal Aviation Administration, FAA Southwest Regional Office, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone 817–222–5104; email *mitch.soth@faa.gov.*

**SUPPLEMENTARY INFORMATION:**

### Background

On April 10, 2023, Skyryse applied for a supplemental type certificate (STC) for the installation of novel control inputs and an FBW system in the Model R66 helicopter. The Robinson Model R66 helicopter, currently approved under Type Certificate No. R00015LA, is a single-engine, five-passenger helicopter with a maximum takeoff weight of 2,700 pounds.

Title 14 CFR 27.171, 27.173, and 27.175 establish the minimum requirements for static longitudinal stability for operation under visual flight rules, and appendix B of part 27, sections IV and VII, ''Airworthiness Criteria for Helicopter Instrument Flight,'' provides the airworthiness criteria for helicopter instrument flight. However, these requirements are inadequate for the Robinson Model R–66 helicopter as modified by Skyryse because the longitudinal control laws may permit neutral or negative static stability rather than requiring positive static stability throughout the approved flight envelope.

### Type Certification Basis

Under the provisions of § 21.101, Skyryse must show that the Robinson Model R66 helicopter, as changed, continues to meet the applicable provisions of the regulations incorporated by reference in Type Certificate No. R00015LA or with the regulations in effect on the date of the application for the change.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 27) do not contain adequate or appropriate safety standards for the Robinson Model R66 helicopter because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the applicant apply for an STC to modify any other model included on the same type certificate to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Robinson Model R66 helicopter must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34, and the noise certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.101.

### Novel or Unusual Design Features

The Robinson Model R66 helicopter will incorporate the following novel or unusual design feature:

A four-axis full authority digital FBW FCS that provides aircraft control through pilot control inputs or coupled autopilot modes in addition to degraded modes.

### Discussion

The Skyryse Robinson Model R66 helicopter is configured with an FBW FCS, which needs to be evaluated for

acceptable static stability characteristics.

For conventional rotorcraft having mechanical linkages from the primary cockpit flight controls to the rotor, static longitudinal stability means that a pull displacement or force on the cyclic will result in a reduction of speed relative to the trim speed, and that a push displacement or force will result in a higher speed relative to the trim speed. Acceptable longitudinal stability is necessary for the following reasons:

- Airspeed change cues are provided to the pilot through increased and decreased forces on the controller.
- Short periods of unattended control of the rotorcraft do not result in significant changes in attitude, airspeed, or load factor.
- A predictable pitch response is provided to the pilot.
- An acceptable level of pilot workload, to attain and maintain trim speed and attitude, is provided to the pilot.
- Longitudinal stability provides gust stability.

The pitch control movement of the cyclic for the FBW FCS is an attitude command, which results in a rotor movement to attain the commanded pitch attitude. The flight path commanded by the initial cyclic input will remain stick-free until the pilot gives another command. This control function is applied during ''normal'' control laws within the approved flight envelope.

As detailed in § 27.173(b) and considered in Advisory Circular (AC) 27.173(A), ''Static Longitudinal Stability,'' which is contained within AC 27–1B, ''Certification of Normal Category Rotorcraft,'' and the positive control force stability requirements in appendix B to part 27, sections IV and VII, the slope of the control position (cyclic) versus the airspeed curve must be positive (*i.e.,* provide positive static stability) throughout the full range of altitude for which certification is requested with the throttle and collective pitch held constant.

The design of the Skyryse FBW FCS is such that the static stability requirements identified under part 27 and appendix B, section IV, may not be met for all flight conditions.

The special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

**Discussion of Comments**

The FAA issued notice of proposed special conditions No. FAA–2025–2303 for the Robinson Model R66 helicopter, which was published in the **Federal Register** on November 21, 2025 (90 FR 52569).

The FAA received a comment from the Citizens Rulemaking Alliance, which raised several issues.

The commenter stated the FAA improperly relied on ''good cause'' to bypass the notice and comment procedures and 30-day delayed effective date under the Administrative Procedure Act. The commenter requested that the FAA withdraw the immediate effectiveness of the special conditions and republish them as proposed special conditions with a reasonable comment period.

The FAA disagrees. As noted in 14 CFR 11.38, the Administrative Procedure Act does not require notice and comment for special conditions, which are rules of particular applicability. Nonetheless, the FAA did provide notice and comment on these special conditions. Citizens Rulemaking Alliance submitted this comment in response to a notice of proposed special condition for which the FAA provided a 45-day comment period. In addition, these final special conditions are effective 30 days after publication in the **Federal Register**. Therefore, no change is necessary.

The commenter stated that the FAA failed to provide the technical rationale for its deviation from part 27 requirements and requested that the FAA place in the docket a non-proprietary, substantive summary of the technical basis and safety case. The commenter requested that the FAA include a description of the modified flight control architecture and control laws, a comparative assessment of the applicable regulations, flight test plans and results, failure modes and effects analysis excerpts, and proposed rotorcraft flight manual changes.

The FAA disagrees. The preamble of the notice of proposed special conditions explains the novel and unusual design feature and how the current requirements in part 27 are not applicable to FBW rotorcraft with indirect flight controls that have extensively augmented stability. The preamble also explains the FAA's justification for the safety standards in the special conditions. The additional information requested by the commenter is proprietary. The Freedom of Information Act (5 U.S.C. 552) and the Trade Secrets Act (18 U.S.C. 1905) prohibit the FAA from disclosing such data.

The commenter stated that the special conditions are a ''novel policy'' under Executive Order 12866 and requested that the FAA submit them to the Office of Information and Regulatory Affairs for a significance determination.

The FAA disagrees. Special conditions are not subject to review under Executive Order 12866, which only applies to rules of general applicability.

Lastly, the commenter stated that the FAA failed to comply with the Regulatory Flexibility Act (5 U.S.C. 601–612) and requested that the FAA include in the docket its assessment of the burden of the special conditions on small entities.

The FAA disagrees. Special conditions are not subject to the Regulatory Flexibility Act, which only applies to general notices of proposed rulemaking.

**Applicability**

As discussed above, these special conditions are applicable to the Robinson Model R66 helicopter. Should Skyryse apply at a later date for an STC to modify any other model included on Type Certificate No. R00015LA to incorporate the same novel or unusual design feature, these special conditions would apply to that model as well.

**Conclusion**

This action affects only a certain novel or unusual design feature on the Model R66 helicopter. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the rotorcraft.

**List of Subjects in 14 CFR Part 27**

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

**Authority Citation**

The authority citation for these special conditions is as follows:

**Authority:** 49 U.S.C. 106(f), 106(g), 40113, 44701–44702, 44704.

**The Special Conditions**

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for the Robinson Helicopter Company Model R66 helicopter, as modified by Skyryse.

In lieu of the requirements of §§ 27.173(b) and 27.175 for operation under visual flight rules and the airworthiness criteria for helicopter instrument flight in appendix B to part 27, sections IV and VII, the following special conditions apply:

The rotorcraft must be shown to have suitable longitudinal stability in any condition normally encountered in

service, including the effects of atmospheric disturbance. The showing of suitable static longitudinal stability must be based primarily on a positive control movement (positive control sense of motion as referenced in AC 27.173A), in addition to rotorcraft handling qualities by assessing pilot workload, cues, and pilot compensation for specific test procedures during the flight test evaluation.

Issued in Fort Worth, Texas, on April 29, 2026.

**Jorge R. Castillo,**

*Manager, Technical Policy Branch, Policy and Standards Division, Aircraft Certification Service.*

[FR Doc. 2026–08938 Filed 5–5–26; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 866

**[Docket No. FDA–2026–N–4644]**

## Medical Devices; Immunology and Microbiology Devices; Classification of the Device To Preserve and Stabilize Relative Abundances of Microbial Nucleic Acids in Clinical Samples

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final amendment; final order.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying the device to preserve and stabilize relative abundances of microbial nucleic acids in clinical samples 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 device to preserve and stabilize relative abundances of microbial nucleic acids in clinical samples. 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 November 3, 2021.

**FOR FURTHER INFORMATION CONTACT:** Himani Bisht, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3106, Silver Spring, MD 20993–0002, 301–796–6189, *Himani.Bisht@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Background

Upon request, FDA (the Agency or we) has classified the device to preserve and stabilize relative abundances of microbial nucleic acids in clinical samples 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 June 15, 2020, FDA received DNA Genotek Inc.'s request for De Novo classification of the OMNIgene GUT Dx 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