



September 26, 2025

Canon Medical Systems Corporation  
% Jonathan Toy  
Manager, Regulatory Affairs  
Canon Medical Systems, USA  
2441 Michelle Drive  
TUSTIN, CA 92780

Re: K251645

Trade/Device Name: Self-Propelled CT Scan Base Kit, CGBA-035A;  
Alphenix, INFX-8000C/B, INFX-8000C/S, V9.6 with Calculated DAP  
Regulation Number: 21 CFR 892.1750  
Regulation Name: Computed Tomography X-Ray System.  
Regulatory Class: Class II  
Product Code: JAK, OWB  
Dated: August 28, 2025  
Received: August 28, 2025

Dear Jonathan Toy:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A large, light blue watermark of the letters "FDA" is visible in the background. Overlaid on this watermark is a handwritten signature in black ink that reads "Lu Jiang".

Lu Jiang, Ph.D.  
Assistant Director  
Diagnostic X-Ray Systems Team  
DHT8B: Division of Radiological Imaging  
Devices and Electronic Products  
OHT8: Office of Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K251645

Device Name

Self-Propelled CT Scan Base Kit, CGBA-035A;  
Alphenix, INFX-8000C/B, INFX-8000C/S, V9.6 with Calculated DAP

Indications for Use (Describe)

Self-Propelled CT Scan Base Kit, CGBA-035A:

The movable gantry base unit allows the Aquilion ONE (TSX-308A) system to be installed in the same procedure room as the INFX-8000C system, enabling coordinated clinical use within a shared workspace. This configuration provides longitudinal positioning along the z-axis for image acquisition.

Alphenix, INFX-8000C/B, INFX-8000C/S, V9.6 with Calculated DAP:

This device is a digital radiography/fluoroscopy system used in a diagnostic and interventional angiography configuration. The system is indicated for use in diagnostic and angiographic procedures for blood vessels in the heart, brain, abdomen and lower extremities. The Calculated Dose Area Product (DAP) feature provides an alternative method for determining dose metrics without the use of a physical area dosimeter. This function estimates the cumulative reference air kerma, reference air kerma rate, and cumulative dose area product based on system parameters, including X-ray exposure settings, beam hardening filter configuration, beam limiting device position, and region of interest (ROI) filter status. The calculation method is calibration-dependent, with accuracy contingent upon periodic calibration against reference measurements.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**510(k) SUMMARY**

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92

**1. SUBMITTER'S NAME**

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**2. OFFICIAL CORRESPONDENT**

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**5. ESTABLISHMENT REGISTRATION**

9614698

**6. DATE PREPARED**

May 29, 2025

**7. TRADE NAME(S)**

Self-Propelled CT Scan Base Kit, CGBA-035A

**8. COMMON NAME**

Computed Tomography X-Ray System

**9. CLASSIFICATION PANEL**

Radiology

**10. DEVICE CLASSIFICATION**

a) Classification Name: Computed Tomography X-Ray System

b) Regulation Number: 21 CFR 892.1750

c) Regulation Class: Class II

**11. PRODUCT CODE**

JAK

**12. PERFORMANCE STANDARD**

This device conforms to applicable Performance Standards for Ionizing Radiation Emitting Products [21 CFR Subchapter J, Part 1020].

**13. PREDICATE DEVICE**

Product	Marketed by	Regulation Number	Regulation Name	Product Code	510(k) Number	Clearance Date
Aquilion ONE Self-Propelled Scan Base Kit for IVR-CT, CGBA-034A (Primary Predicate)	Canon Medical Systems USA	21 CFR 892.1750	Computed tomography X-ray system	JAK	K182223	September 14, 2018
Aquilion ONE (TSX-308A/3) V1.5 (Secondary Predicate)	Canon Medical Systems USA	21 CFR 892.1750	Computed tomography X-ray system	JAK	K242403	December 23, 2024

**14. REASON FOR SUBMISSION**

Modification of a cleared device.

The purpose of this submission is to seek market clearance for Self-Propelled CT Scan Base Kit, CGBA-035A.

**15. SUBMISSION TYPE**

Traditional 510(k)

**16. DEVICE DESCRIPTION**

The Alphenix 4DCT is composed of the INFX-8000C interventional angiography system and the dynamic volume CT system, Aquilion ONE, TSX-308A. This combination enables patient access and efficient workflow for interventional procedures. **Self-Propelled CT Scan Base Kit, CGBA-035A**, is an optional kit intended to be used in conjunction with an Aquilion ONE / INFX-8000C based IVR-CT system. This device is attached to the Aquilion ONE CT gantry to support longitudinal movement and allow image acquisition in the z-direction (Z-axis), both axial and helical. When this option is installed, the standard CT patient couch is replaced with the fixed catheterization table utilized by the interventional x-ray system, INFX-8000C. The **Self-Propelled CT Scan Base Kit, CGBA-035A**, will be used as part of an Aquilion ONE / INFX-8000C based IVR-CT system. Please note, the intended uses of the Aquilion ONE CT System and the INFX-8000C

Interventional X-Ray System remain the same. There have been no modifications made to the imaging chains in these FDA cleared devices and the base system software remains the same. Since both systems will be installed in the same room and to prevent interference during use, system interlocks have been incorporated into the systems.

Please note: The terms “Self-Propelled Scan Base”, “Moving Base” and “Movement Base” are used interchangeably throughout this submission. They all refer to the same unit.

**17. INDICATIONS FOR USE**

The movable gantry base unit allows the Aquilion ONE (TSX-308A) system to be installed in the same procedure room as the INFX-8000C system, enabling coordinated clinical use within a shared workspace. This configuration provides longitudinal positioning along the z-axis for image acquisition.

**18. SUBSTANTIAL EQUIVALENCE**

This device is substantially equivalent to Aquilion ONE Self-Propelled Scan Base Kit for IVR-CT, CGBA-034A which received premarket clearance under K182223, marketed by Canon Medical Systems USA.

**Self-Propelled CT Scan Base Kit, CGBA-035A**, incorporates modifications to the cleared devices in order to allow the self-propelled scan base unit to be connected to an Aquilion One CT gantry, establishing the combined Aquilion ONE / INFX-8000C based IVR-CT system. This allows the CT system to acquire images in the z-direction (Z-axis) when a fixed catheterization table is used for patient support instead of a dedicated CT patient couch. The indications for use, method of operation including the imaging chain, base software and manufacturing process of the CT and Interventional XR systems remain unchanged from the cleared devices.

See below for a brief summary of changes from Self-Propelled CT Scan Base Kit, CGBA-035A:

	<b>Subject Device</b>	<b>Predicate Device</b>
<b>Device Name, Model Number</b>	<b>Self-Propelled CT Scan Base Kit, CGBA-035A</b>	<b>Self-Propelled Scan Base Kit for IVR-CT, CGBA-034A</b>
<b>510(k) Number</b>	<b>This submission</b>	<b>K182223</b>
<b>CT System</b>	Aquilion ONE (TSX-308A)	Aquilion ONE (TSX 305A) (Modified as K213504)
<b>X-Ray System</b>	Alphenix, INFX-8000C/B, INFX-8000C/S, V9.6 with Calculated DAP	Alphenix, INFX-8000C/B, INFX-8000C/S, V9.2 (Modified as K210900)
<b>Gantry tilting</b>	Max. +/-30°	Max. +/-28°
<b>Gantry movement speed</b>	High speed 130 mm/s, Low speed 5 mm/s	High speed 100 mm/s, Low speed 5 mm/s
<b>Helical scan speed</b>	0.8mm/s to 130 mm/s	10 mm/s to 96 mm/s

**19. SAFETY**

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards.

CT system of this device is in conformance with the applicable parts of the IEC 60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-1-6, IEC 60601-1-9, IEC 60601-2-28, IEC 60601-2-44, IEC 60825-1, IEC 62304, IEC 62366-1, IEC 81001-5-1, NEMA XR-25, NEMA XR-26 and NEMA XR-29.

X-Ray system of this device is in conformance with the applicable parts of the IEC 60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-1-6, IEC 60601-2-28, IEC 60601-2-43, IEC 62304, IEC 62366-1, IEC 81001-5-1, ISO 17664-2, IEC TR 60601-4-2.

Additionally, this device complies with all applicable requirements of the radiation safety performance standards, as outlined in 21 CFR §1010 and §1020.

**20. TESTING****Performance Testing – Bench**Evaluation of the Extension Tabletop

Image quality evaluation for the extension tabletop combined with CGBA-035A was performed, utilizing phantoms, to confirm there is no significant artifact in acquired images and that the CT number of water in the acquired images is within a specified range. The test results found no abnormalities within the extension tabletop images, and the CT number of water in the acquired images was within the specified range.

Clearance Check for CGBA-035A

This test evaluated the clearance of the scan field, permissible tilt range, tabletop height, and gantry slide sensor position, considering the clearance between the gantry and tabletop. It evaluated whether the clearance between the patient and the dome is more than the reference value within the maximum permissible tilt range at the UP-LIMIT position as well as the necessity of gantry contact detection switches. Results of this evaluation defined the clearance of the scan field, permissible gantry tilt range, tabletop height, and gantry slide sensor positions as well as confirmed that when the table is at the table UP-LIMIT position, the clearance in the body-thickness direction is more than the reference value. Additionally, gantry detection switches were determined not to be required, due to sufficient clearance when considering the interference between the gantry dome and the tabletop, other units mounted on the table, or interference between the patient/operator having been established.

Vibration Test using a Ball Phantom

Image quality evaluation was performed by imaging a ball phantom using a system with CGBA-035A to check for differences in image quality due to the rotation speed, in comparison with images acquired using a conventional system (system with couch-top sliding). The test results found no observable significant difference in image quality due to the difference in rotation speed.

#### Movement Speed of Gantry Movement Base

This test was performed to confirm that the movement speed of the IN and OUT operation of the gantry movement base satisfied the specified criteria, by measuring the time required for the gantry movement base to travel a designated distance. By testing both high and low speed movement modes of the gantry movement base, it was determined that the movement speed of the gantry movement base satisfied the allowable value criteria.

#### Stop Position Accuracy

Testing was performed to confirm that the stop position accuracy of the gantry movement base did not exceed the allowable stop position displacement value, and the position displayed correctly on the gantry operating panel. The test results found that all criteria were satisfied.

#### Slide Running

Testing was performed by applying a load equivalent to system operation for 10 years to confirm that the cable guide unit, the LM guides, the racks, the rail covers, the sliding parts of the rail covers, and the limit switches maintain acceptable performance. The test results confirmed that the durability performance of the parts related to the cable guides, the LM guides, the racks, the parts related to the rail covers, and the limit switches satisfy the specified criteria.

#### Emergency Stop

Testing was performed to confirm that when the emergency stop is operated, the electrical drive circuit of the gantry movement base is turned OFF, no harm is caused, the gantry movement base can be moved manually and after the emergency stop status is cleared, the gantry movement base can resume normal operation. The test results found that all criteria were satisfied.

#### Interlock Test

Testing was performed to confirm that the operations of gantry movement base sliding, gantry tilting, and scanning, and interlocking functions work as designed. In accordance with pre-established criteria, various operations of the gantry were performed to test interlocking mechanisms of the contact detection switches, movement position detection sensor, table up/down sensor, system operation and control priority, X-ray irradiation, sensor error detection, etc. The test results confirmed that all interlocking functions work normally.

Risk analysis and verification/validation testing conducted through bench testing demonstrate that the established specifications for the device have been met. Testing of the modified system was conducted in accordance with the applicable standards published by the International Electromechanical Commission (IEC) for Medical Devices , CT Systems and X-Ray Systems.

Software Documentation for a Basic Documentation Level, per the FDA guidance document, "Content of Premarket Submissions for Device Software Functions" issued on June 14, 2023, was determined appropriate. This documentation includes justification for the Basic Documentation Level determination as well as testing which demonstrates that the verification and validation requirements have been met.

Cybersecurity documentation followed FDA cybersecurity premarket guidance document “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions” issued on September 27, 2023.

**21. CONCLUSION**

The **Self-Propelled CT Scan Base Kit, CGBA-035A** is substantially equivalent to the predicate device. The subject device functions in a manner similar to and is intended for the same use as the predicate device, as described in the labeling. Based upon the bench testing, successful completion of software validation, application of risk management and design controls, it is concluded that this device is safe and effective for its intended use.

**510(k) SUMMARY**

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92

**1. SUBMITTER'S NAME**

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**5. ESTABLISHMENT REGISTRATION**

9614698

**6. DATE PREPARED**

May 29, 2025

**7. TRADE NAME(S)**

Alphenix, INFX-8000C/B, INFX-8000C/S, V9.6 with Calculated DAP

**8. COMMON NAME**

Interventional Fluoroscopic X-ray System

**9. CLASSIFICATION PANEL**

Radiology

**10. DEVICE CLASSIFICATION**

- a) Classification Name: Image-Intensified Fluoroscopic X-ray System
- b) Regulation Number: 21 CFR 892.1650
- c) Regulation Class: Class II

**11. PRODUCT CODE**

OWB

**12. PERFORMANCE STANDARD**

This device conforms to applicable Performance Standards for Ionizing Radiation Emitting Products [21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard].

**13. PREDICATE DEVICE**

Product	Marketed by	Regulation Number	Regulation Name	Product Code	510(k) Number	Clearance Date
Alphenix, INFX-8000C/B, INFX-8000C/S, V9.2	Canon Medical Systems USA	21 CFR 892.1650	Image-intensified fluoroscopic X-ray system	OWB	K210900	April 12, 2021

**14. REASON FOR SUBMISSION**

Modification of a cleared device

**15. SUBMISSION TYPE**

Traditional 510(k)

**16. DEVICE DESCRIPTION**

The **Alphenix, INFX-8000C/B, INFX-8000C/S, V9.6 with Calculated DAP**, is an interventional x-ray system with a ceiling suspended C-arm as its main configuration. Additional units include a patient table, x-ray high-voltage generator and a digital radiography system. The C-arms can be configured with designated x-ray detectors and supporting hardware (e.g. x-ray tube and diagnostic x-ray beam limiting device). The INFX-8000C system incorporates a Calculated Dose Area Product (DAP) feature, which provides an alternative method for determining dose metrics without the use of a physical area dosimeter. This function estimates the cumulative reference air kerma, reference air kerma rate, and cumulative dose area product based on system parameters, including X-ray exposure settings, beam hardening filter configuration, beam limiting device position, and region of interest (ROI) filter status. The calculation method is calibration-dependent, with accuracy contingent upon periodic calibration against reference measurements.

**17. INDICATIONS FOR USE**

This device is a digital radiography/fluoroscopy system used in a diagnostic and interventional angiography configuration. The system is indicated for use in diagnostic and angiographic procedures for blood vessels in the heart, brain, abdomen and lower extremities.

The Calculated Dose Area Product (DAP) feature provides an alternative method for determining dose metrics without the use of a physical area dosimeter. This function estimates the cumulative reference air kerma, reference air kerma rate, and cumulative dose area product based on system parameters, including X-ray exposure settings, beam hardening filter configuration, beam limiting device position, and region of interest (ROI) filter status. The calculation method is calibration-dependent, with accuracy contingent upon periodic calibration against reference measurements.

**18. SUBSTANTIAL EQUIVALENCE**

The device is substantially equivalent to the Alphenix, INFX-8000C/B, INFX-8000C/S, V9.2, which received premarket clearance under K210900, marketed by Canon Medical Systems USA.

**Alphenix, INFX-8000C/B, INFX-8000C/S, V9.6 with Calculated DAP**, which provides the ability for dose to be calculated and displayed based on X-ray conditions without relying on the conventional dose chamber and meter. Testing was conducted to demonstrate that the calculation of dose by Calculated DAP is equivalent to that by the dosimeter in the predicate INFX-8000C device, and the accuracy of the dose display meets IEC standards. Additionally, assessments were conducted to verify Calculated DAP would maintain its accuracy throughout the aging and lifespan of the INFX-8000C. The indications for use, method of operation, base software and manufacturing process of the XR system remain unchanged from the cleared device.

See below for a brief summary of changes from Alphenix, INFX-8000C/B, INFX-8000C/S, V9.6 with Calculated DAP:

	<b>Subject Device</b>	<b>Predicate Device</b>
<b>Device Name, Model Number</b>	<b>Alphenix, INFX-8000C/B, INFX-8000C/S, V9.6 with Calculation DAP</b>	<b>Alphenix, INFX-8000C/B, INFX-8000C/S, V9.2</b>
<b>510(k) Number</b>	<b>This submission</b>	<b>K210900</b>
Dosimeter	PTW (Option) Area dose display by calculation (Standard)	PTW (Standard)

**19. SAFETY**

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards.

This device is in conformance with the applicable parts of the IEC 60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-1-6, IEC 60601-2-28, IEC 60601-2-43, IEC 62304, IEC 62366-1, IEC 81001-5-1, ISO 17664-2, IEC TR 60601-4-2.

Additionally, this device complies with all applicable requirements of the radiation safety performance standards, as outlined in 21 CFR §1010 and §1020.

**20. TESTING**

**Performance Testing – Bench**

Dose Calculation Evaluation

A system evaluation was conducted for the dose calculation function to confirm that the accuracy of the dose display meets IEC standards. Since dosimeters are beam quality dependent, the error from the actual dose value changes depending on the tube voltage; accuracy was checked under various conditions by comparison with the actual measurement value on the dosimeter and not with the value of the area dosimeter. It was concluded that the accuracy of the dose calculation function met the IEC standards and was judged to be satisfactory.

Risk analysis and verification/validation testing conducted through bench testing demonstrate that the established specifications for the device have been met. Testing of the modified system was conducted in accordance with the applicable standards published by the International Electromechanical Commission (IEC) for Medical Devices and XR Systems.

Software Documentation for a Basic Documentation Level, per the FDA guidance document, "Content of Premarket Submissions for Device Software Functions" issued on June 14, 2023, was determined appropriate. This documentation includes justification for the Basic Documentation Level determination as well as testing which demonstrates that the verification and validation requirements have been met.

Cybersecurity documentation followed FDA cybersecurity premarket guidance document "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" issued on September 27, 2023.

## **21. CONCLUSION**

The **Alphenix, INFX-8000C/B, INFX-8000C/S, V9.6 with Calculated DAP** is substantially equivalent to the predicate device. The subject device functions in a manner similar to and is intended for the same use as the predicate device, as described in the labeling. Based upon the bench testing, successful completion of software validation, application of risk management and design controls, it is concluded that this device is safe and effective for its intended use.