UC-CARE , Ltd.
Hadas Sheynise
SQA and V&V Manager
Apollo Bldg., POB. 310,
Yokneam, 2069200
Israel

July 30, 2026

Re: K260161
Trade/Device Name: SmartGuide Disposable Guides and Grids
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: ITX
Dated: June 30, 2026
Received: June 30, 2026

Dear Hadas Sheynise:

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,

Digitally signed by Michael D. O'hara -S
Date: 2026.07.30 13:47:03 -04'00'

For

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260161

Device Name
SmartGuide Disposable Needle Guides and Grids

Indications for Use *(Describe)*
SmartGuide Disposable Needle Guides and Grids are used to assist and aid physicians in performing an endocavity diagnosis ultrasound needle guided procedure using guided intervention by providing fixed guiding for the precise insertion of linear instruments, such as needles. The Needle Guides and Grids are designed to aid adult patient population, in need of a biopsy, via the use of a needle, during an ultrasound procedure by retaining the needle tip and barrel within the ultrasound beam.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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28 July 2026

510(k) Summary (K260161)

UC-Care Ltd.'s SmartGuide

1. **Submitter Information**

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Date of Preparation: 17 June, 2026

Identification of Subject Device

Name of Device: SmartGuide Disposable Needle Guides and Grids
Common or Usual Name: Disposable Needle Guides and Grids
Proprietary/Trade name: SmartGuide Disposable Needle Guides and Grids
Classification Name: Diagnostic ultrasonic transducer accessories
Regulation Number: 21 CFR 892.1570
Product Code: ITX
Regulatory Class: II

2. **Identification of Predicate**

Device Name	510(k) Number	Type
Disposable Needle Guides and Grids	K223689	Primary
Disposable Guides KDNG00	K180970	Reference
GTK Disposable needle Guides	K170741	Reference

3. Device Description

The SmartGuide Disposable Needle Guides and Grids (hereinafter referred to as "SmartGuide") is a single-use, disposable polycarbonate needle guide, provided sterile (EtO) and individually packaged in Tyvek®/PET-PE sterile peel pouches.

The SmartGuide is used in conjunction with reusable Navigo Workstation sensor fixators, which attach to compatible ultrasound probes and are designed to secure the SmartGuide and the Navigo system probe sensor during use.

The SmartGuide is designed to mechanically guide a needle or other linear insertion tool in Transperineal biopsy procedures in multiple available tracks located within the ultrasound US image plane (centralized to the ultrasound probe).

The SmartGuide Disposable Needle Guides and Grids are classified as a Class II medical device under 21 CFR 892.1570 (Diagnostic ultrasonic transducer accessories), Product Code ITX.

4. Intended Use and Indication for Use statement

Indication For Use

SmartGuide Disposable Needle Guides and Grids are used to assist and aid physicians in performing an endocavity diagnosis ultrasound needle guided procedure using guided intervention by providing fixed guiding for the precise insertion of linear instruments, such as needles. The Needle Guides and Grids are designed to aid adult patient population, in need of a biopsy, via the use of a needle, during an ultrasound procedure by retaining the needle tip and barrel within the ultrasound beam.

Intended Use

The SmartGuide provides fixed guiding of the precise insertion of linear instruments, such as needles through mechanical means with the use of diagnostic ultrasound equipment. The Needle Guide and Grids are attached over the transducer/ probe/ scanning instruments. The device provides a fixed path for the imaging guidelines for visualizing guided instrument placement procedures. UC-CARE SmartGuide Needle Guides and Grids are furnished sterile; single use patient/ procedure, and disposable. The Needle Guides and Grids are intended for use by clinicians, in clinical and hospital settings, to guide linear instruments during Transperineal ultrasound procedure that require the precision use of a needle.

5. Summary of Technological Characteristics

Subject, Predicate Device and Reference Devices' indications for use place the SmartGuide Needle Guides and Grids and AMD (510k# K223689) /KOELIS (510k# K180970)/ GeoTek (510k# K170741) Ultrasound Needle Guides in device body contact categories as follows:

a. Surface devices, intact skin / mucosal membranes/ breached surfaces, limited contact duration (<24 hours)
b. External communicating devices, blood path indirect, tissue communicating limited contact duration (<24 hours)

Subject and Predicate Device have a similar Intended Use and Subject, Predicate device, and Reference devices (K180970, K170741) provide mechanical means for performing needle/ instrument guided procedures with the use of diagnostic ultrasound transducers. These devices provide the same fixed path for the needle or instrument that when coupled by the ultrasound system software corresponds to the on-screen imaging guidelines for visualizing guided instrument placement procedures. Predicate device, Reference Devices, and Subject device are furnished sterile; and the entire guide is single use patient/ procedure, disposable.

The principles of operation of the SmartGuide are similar to those of the predicate and reference devices and include:

- Placement of a probe attachment bracket onto the ultrasound transducer using locating and fixation features
- Securing the disposable needle guide to the transducer using a mechanical locking mechanism
- Maintaining a fixed spatial relationship between the transducer and the needle guide to ensure accurate alignment of the needle within the ultrasound imaging plane
- Releasing the locking mechanism to remove the needle guide from the transducer after use

The primary predicate device and the SmartGuide both utilize a mechanical attachment bracket to secure the disposable needle guide to the ultrasound transducer and to maintain stable and repeatable needle guidance during use. In the primary predicate device, the mounting bracket and cannula are integrated into a single disposable component that attaches externally to the transducer. In the SmartGuide, the disposable needle guide is mounted onto a probe attachment bracket (Navigo workstation fixator), which is a reusable component that is part of the previously cleared Navigo System (K250664).
The use of the Navigo probe attachment bracket does not alter the intended use, principle of operation, or functional performance of the SmartGuide. The bracket does not introduce additional patient contact beyond that associated with the disposable needle guide and serves solely as a mechanical fixation interface between the transducer and the guide. Accordingly, this design configuration demonstrates substantial equivalence to the predicate device design.

Substantial Equivalence (Comparison Table)

	Subject Device	**Primary Predicate Device** K223689	**Reference Device** K180970	**Reference Device** K170741
Company	UC-Care Ltd.	Advance Medical Designs	KOELIS	Geotek
Device Name	SmartGuide Disposable Needle Guides and Grids	Disposable Needle Guides and Grids	Disposable Guides KDNG00	GTK Disposable needle Guides
Regulation Number	21 CFR 892.1570	21 CFR 892.1570	21 CFR 892.1570	21 CFR 892.1570
Device Class	Class II	Class II	Class II	Class II
Product Code	ITX	ITX	ITX	ITX
Indications for Use	SmartGuide Disposable Needle Guides are used to assist and aid physicians in performing an endocavity diagnosis ultrasound needle guided procedure using guided intervention by providing fixed guiding for the precise insertion of linear instruments, such as needles. The Needle Guides and Grids are designed to aid adult patient population, in need of a biopsy, via the use of a needle, during an ultrasound procedure by retaining the needle tip and barrel within the ultrasound beam.	Disposable Needle Guides and Grids are used to assist and aid physicians in performing an endocavity diagnosis ultrasound needle guided procedure using guided intervention by providing fixed guiding for the precise insertion of linear instruments, such as needles. The Needle Guides and Grids are designed to aid adult patient population, in need of a biopsy of an internal organ, or internal delivery or removal of fluid within the body cavity, via the use of a needle, during an ultrasound procedure by retaining the needle tip and barrel within the ultrasound beam.	The disposable guide KDNG00 is dedicated for endocavity diagnosis ultrasound needle guided procedure. it is intended for clinicians and assistant clinicians, in clinic and hospital, to guide linear instrument with a transrectal approach.	GTK disposable Needle Guides when used in conjunction with ultrasound system transducer where configuration is suitable (e.g Aloka, Alpinion, BK ,Esaote, GE, Hitachi, Medison, Mindray, Philips, Toshiba, Siemens and Shimadzu ultrasound systems) and attached to the ultrasound system's transducers, is to facilitate proper needle placement to access anatomical structures.
Intended Use	The Subject Device provides fixed guiding of	The Subject Device provides fixed guiding of the	The disposable guide KDNG00 provides a fixed	NA

	the precise insertion of linear instruments, such as needles through mechanical means with the use of diagnostic ultrasound equipment. The Needle Guide and Grids are attached over the transducer/ probe/ scanning instruments. The device provides a fixed path for the imaging guidelines for visualizing guided instrument placement procedures. UC-CARE SmartGuide Needle Guides and Grids are furnished sterile; single use patient/ procedure, and disposable. The Needle Guides and Grids are intended for use by clinicians in clinical and hospital settings, to guide linear instruments during Transperineal ultrasound procedure that require the precision use of a needle.	precise insertion of linear instruments, such as needles through mechanical means with the use of diagnostic ultrasound equipment. The Needle Guide and Grid is attached over the transducer/ probe/ scanning instruments. The device provides a fixed path for the imaging guidelines for visualizing guided instrument placement procedures. Advance Medical Designs (AMD) Needle Guides and Grids are furnished sterile; single use patient/ procedure, and disposable. The single use, disposable feature helps prevent transfer of microorganisms, body fluid, and particulate material to the patient and healthcare worker during reuse of the transducer. The Needle Guides and Grids are intended to clinicians and assistant clinicians, in clinical and hospital settings, to guide linear instruments during any ultrasound	path for the needle that when coupled by the ultrasound system software corresponds to on-screen imaging guidelines for visualizing guided instrument placement procedures.	

		procedure that require the precision use of a needle.		
Design	SmartGuide Designs Needle Guide and Grid is a plastic guide designed to be clipped on to an ultrasound probe, with an entry cone to easily introduce the needle into the channel. **Fixation mechanism** of the Guide on the probe: The guide is fixed on the probe with a reusable clip (Navigo Fixator) to allow the needle guide stability on the transducer and a lateral screw to fix the guide axial position within the clip.	Advance Medical Designs Needle Guide and Grid is a plastic guide designed to be clipped on to an ultrasound probe, with an entry cone to easily introduce the needle into the channel. **Fixation mechanism** A clip to allow the needle guide stability on the transducer and 2 pins for attachment in the notches for the probe.	Plastic guide designed to be clipped on an endocavity ultrasound probe. An entry cone to easily introduce the needle into the tube. **Fixation mechanism** A clip to allow the needle guide stability on the transducer and 2 pins for attachment in the notches for the probe.	The GTK Disposable Needle Guides are polymeric needle guides made from molded ABS/PC plastic and some models have a stainless cannula. The GTK disposable guides hold both the US probe and the needle guides in place relative to each other while the US guided biopsy is being performed. The GTK disposable needle guides is and assembly of 1 or 2 components, either just a carriage or a carriage with a rail (cannula).
Materials of Construction	Medical Grade Polycarbonate The material have met the requirements of ISO 10993-1 for biocompatibility.	Medical Grade Thermoplastic ABS Polypropylene 304 Stainless Steel All materials have met the requirements of ISO 10993-1 for biocompatibility.	Medical Grade Polycarbonate All materials have met the requirements of ISO 10993-1 for biocompatibility.	ABS or Polycarbonate
Safety/ Biocompatibility	Meets ISO 10993-1 biocompatibility requirements for	Meets ISO 10993-1 biocompatibility requirements	Meets ISO 10993-1 biocompatibility requirements	NA

	limited contact duration: • Surface device – intact skin contact • External communicating indirect tissue contact (via biopsy needle only) **Demonstrated to be:** • Non-cytotoxic (ISO 10993-5) • Non-irritating (ISO 10993-23) • Non-sensitizing (ISO 10993-10) • Non-pyrogenic (ISO 10993-11) and • Non-acute systemic toxic (ISO 10993-11)	for limited contact duration: • surface devices of breached or compromised surface • External communicating indirect blood path/tissue contact Demonstrated to be non-toxic, non-sensitizing, non-irritating, non-hemolytic, and nonpyrogenic	for limited contact duration: • surface devices of breached or compromised surface • Externally communicating tissue bone/dentin Demonstrated to be non-toxic, non-sensitizing, non-irritating, (DOES NOT INCLUDE PYROGEN/ HEMO/ OR ACUTE SYSTEMIC)	
Effectiveness	Subject, Predicate, and Reference Devices are designed for secure and aligned fit to the transducer or probe, while not altering the transducer or probe design integrity or function. When used with their intended fixation mechanisms, the design features ensure accurate and consistent needle guidance relative to the transducer. The exterior shapes of the guides are contoured for the patient comfort with no sharp edges. Based on comparison to the primary predicate and the reference devices, UC-CARE SmartGuide needle guides and grids devices have the same intended use and comparable technological characteristics. Therefore, the UC-CARE SmartGuide needle guides and grids are substantially equivalent to the legally marketed primary predicate device, the disposable endocavity needle guide marketed by Advance Medical Designs (K223689).			
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Shelf Life	6 Months	3 years	3 years	5 years
Accessories	None provided.	Ultrasound gel packet and covers.	None provided.	Ultrasound gel packet and covers.
Energy Type	None	None	None	None
Software	None	None	None	None

Non-Clinical Performance Testing

The biological safety of the SmartGuide was evaluated based on its intended use, material composition, and the nature and duration of patient contact, and in comparison, to the predicate and reference devices. The evaluation was conducted using a risk-based approach

in accordance with ISO 10993-1:2018 / EN ISO 10993-1:2020 and FDA guidance *Use of International Standard ISO 10993-1: Biological Evaluation of Medical Devices – Part 1* (September 2023).
Consistent with the predicate and reference devices in terms of limited contact duration, the SmartGuide is intended for use of less than 24 hours. Based on its intended use, the SmartGuide contacts directly the patient's skin and has potential indirect contact with internal non-circulatory tissues through minimal and brief contact mediated by a biopsy or interventional needle. The overall surface area of contact is small and the duration of exposure is short.
Based on this contact characterization and the use of well-characterized medical-grade polycarbonate materials that are also used in the predicate and reference devices, a risk-based biological evaluation determined that cytotoxicity (ISO 10993-5) and irritation (ISO 10993-23) represent the most relevant and sensitive biological endpoints for the SmartGuide ,additionally sensitization (ISO 10993-10), acute systemic toxicity and pyrogenicity (ISO 10993-11) tests were preformed. These endpoints were evaluated on the finished device (See ATT.6.3 Cytotoxicity report_25T_55198_03, ATT.6.4 Irritation report_25T_55198_04, ATT.6.5 Sensitization Test Report _26T_32356_02_03, ATT.6.6 ISO Acute Systemic Toxicity Study Report_26T_32356_05, ATT.6.7 Pyrogen Study_Report_26T_32356_06).

Bench Testing:
According to the FDA guidance titled "*Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions*, *December 20, 2019* " bench performance tests were performed to evaluate the performance, safety, and effectiveness of a medical device under controlled, non-clinical conditions.

The SmartGuide submitted in this premarket notification [510(k)] is a modification of its predicate device Advance Medical Designs (K223689) Disposable Needle Guides and Grids device.

The non-clinical bench performance testing for the SmartGuide utilize similar test methods, standards, and, where applicable, acceptance criteria to those used for the cleared predicate.

1) **Channel alignment testing** - Needle guides were tested on test fixtures to ensure needle path falls within the design tolerances specified for the design.

2) **Needle path and spacing verification testing**- The Needle guide was mounted on the US probe (BK 8848). Needles were inserted through adjacent channels; spacing between the needles was measured.

3) **Equidistance and parallelism test** - By using side view image. Equidistance was demonstrated by assessing the distance between the exit openings (center-to-center). This distance between exit openings was measured (in pixels) by counting the number of pixels between the gray markings of the exit openings (center-to-center).

4) **Cover breach and probe damage testing** - Water leak testing was performed to demonstrate material attachment of needle guide over a cover did not cause damage to cover or probe.

5) **Retention and movement testing** - Force testing was performed on needle guide attachment to ensure a force of 8N would not cause the guide to dislodge.

6**) Needle drag testing Force testing**- was performed by passing a cannula through the needle guide to ensure binding would not occur.

7) **Clinical simulation and Design requirements testing** - A Bench test designed to test the clinical setting during a Navigation procedure via the Navigo system and US system was performed. The design requirements were tested.

Clinical Tests

Clinical tests were not required to demonstrate substantial equivalence.

Conclusions

The UC-Care SmartGuide Disposable Needle Guides and Grids are substantially equivalent to the legally marketed primary predicate device, the Advance Medical Designs Disposable Needle Guides and Grids (K223689). The SmartGuide has the same intended use and indications for use as its primary predicate device, as well as similar technological characteristics and principles of operation.

The technological characteristics of the SmartGuide are similar to those of the primary predicate device, while reference devices (K180970 and K170741) were used to support the evaluation of materials of construction and biological safety. The SmartGuide is sterilized using ethylene oxide (EtO), consistent with the predicate and reference devices, with no differences in the sterilization method or sterility assurance level.

The identified technological and design differences between the SmartGuide and its primary predicate device do not alter the intended use, principle of operation, or functional performance, and do not raise new risks. This was supported by the non-clinical bench performance testing for the SmartGuide utilized similar test methods to those used for the predicate device, and by a risk-based biological evaluation supporting the biological safety of the device for its intended use.

Thus, the UC-Care SmartGuide Disposable Needle Guides and Grids are substantially equivalent to the legally marketed primary predicate device, the Advance Medical Designs Disposable Needle Guides and Grids (K223689).