August 2, 2023

Advance Medical Designs, Inc.
% David Mackie
QA/RA Manager
1241 Atlanta Industrial Drive
MARIETTA GA 30066

Re: K223689
Trade/Device Name: Disposable Needle Guides and Grids
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: ITX
Dated: June 21, 2023
Received: July 3, 2023

Dear David Mackie:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Yanna S. Kang -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223689

Device Name
Disposable Needle Guides and Grids

Indications for Use *(Describe)*
"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."

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
Advance Medical Designs, Inc.
Common Name: Needle Guides & Grids
This summary of Traditional 510(k) Submission of safety and effectiveness of information is being prepared in accordance with the requirements of 21 CFR 807.92.
April 19, 2023
Assigned 510(k) NUMBER: K223689.

1. **Submitter's Identifications:**

510(k) owner's name:	Advance Medical Designs, Inc.
Owner/Operator #:	1037885
Establishment:	Advance Medical Designs, Inc.
Address:	1241 Atlanta Industrial Drive Marietta, GA 30066 USA
Phone Number:	(770) 422-3125
Facility Registration #:	1037885
Contact person:	David Mackie: QA/RA Manager at Advance Medical Designs, Inc.
Phone Number:	(770) 422-3125 ext. 244
e-mail:	mackied@advmeddes.com

2. **Date 510(k) Summary Prepared:** April 19, 2023

3. **Name of Subject Device and Classification Information:**

Trade name:	Disposable Needle Guides and Grids
Regulation Number:	21 CFR 892.1570
510(k) Number:	K223689
Common Name:	Needle Guides & Grids
Classified Name:	Diagnostic ultrasonic transducer accessories
Regulatory Class:	Class II
Product Code:	ITX

4. **Information for the Predicate Device:**

A) *PRIMARY PREDICATE DEVICE*:

Trade Name/Device Name:	Disposable Endocavity Needle / Biopsy Guide
Manufacturer:	CIVCO Medical Instruments Co., Inc.
510(k) Number:	K972514
Regulation Number:	21. CFR 892.1570
Classification Name:	Diagnostic ultrasonic transducer accessories
Regulatory Class:	Class II
Product Code:	ITX

5. Information for Reference Devices:

A) *REFERENCE DEVICE:*

Trade Name/Device Name:	Disposable Guides KDNG00
Manufacturer:	KOELIS
510(k) Number:	K180970
Regulation Number:	21. CFR 892.1570
Classification Name:	Diagnostic ultrasonic transducer accessories
Regulatory Class:	Class II
Product Code:	ITX

B) *REFERENCE DEVICE:*

Trade Name/Device Name:	VitroPRO / Disposable Endocavity Needle Guide
Manufacturer:	CIVCO Medical Instruments Co., Inc.
510(k) Number:	K222052
Regulation Number:	21. CFR 892.1570
Classification Name:	Diagnostic ultrasonic transducer accessories
Regulatory Class:	Class II
Product Code:	ITX

C) *REFERENCE DEVICE:*

Trade Name/Device Name:	Reusable Guide
Manufacturer:	KOELIS
510(k) Number:	K141334
Regulation Number:	21. CFR 892.1570
Classification Name:	Diagnostic ultrasonic transducer accessories
Regulatory Class:	Class II
Product Code:	ITX

Description of Subject Device:

Advance Medical Designs' disposable needle guides & grids devices used to direct needles or instruments along a fixed path to a target location with an ultrasound traducer. They are provided in a variety of sizes to fit different equipment and situations. The Needle Guides and Grids are packaged separately, or within kits, provided sterile, and are labelled as single use only. Each disposable needle guide & grid contains a bracket and needle adapter. Each kit includes a disposable needle guide, a 20ml packet of ASonic® sterile gel, two latex free elastic bands, and a transducer cover (Latex or Latex-Free). The needle guides are non-invasive and have contact with only intact skin.

Needle Guide/Grid:
ABS
Stainless Steel
Polypropylene

Rolled Latex-Free Probe Cover K011265:
Polyisoprene

Rolled Latex Probe Cover K011265:
Latex Rubber

20ml. Sterile Ultrasound Gel 510(k)# K163050:

Device Characteristics of Advance Medical Designs, Inc. Needle Guides and Grids:

- Hypoallergenic, non-irritating
- No toxic effects
- Produced with completely harmless material.
- Does not damage the probe.
- Non-Invasive
- Contact with only intact skin, or with breached surfaces with duration <60 minutes
- Single Use
- Sterile (EtO Sterilization)

Device Identification-Model Numbers and Components:

The differences among the model numbers are limited to the convenience kits they are packaged into, the probe/ transducer/ ultrasound system they are compatible with, and the size specific dimensions indicating which Needle Gauge is appropriate for use. All Product Labels include the name of the specific compatible ultrasound systems that the Needle Guides and Grids are designed to fit. All Product Models are manufactured with the same ABS Polypropylene and injection molded. All accessories and kits are composed of the same accessories:
1) **Advance Medical Designs (AMD) 20ml. Sterile Ultrasound Gel 510(k)# K163050:**
2) **Rolled Latex or Latex Free Probe/Transducer Cover 510(k)# K011265:**

Indications for Use:

"AMD's (Advance Medical Designs) 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."

Intended Use:

The Subject Device 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 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 procedure that require the precision use of a needle.

Comparison to Legally Marketed Device (Predicate and Reference Devices):

Subject, Predicate Device and Reference Devices' indications for use place AMD's Needle Guides and Grids and CIVCO *(510k#* K970514) /KOELIS *(510k#* K180970) 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, K222052) 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 single use, disposable feature helps prevent transfer of microorganisms, body fluids, and particulate material to the patient and healthcare worker during the reuse of the transducer. CIVCO Needle guide kits also provide ultrasound packets and covers which are similar to the subject device kits.

Reference Device (K141334) utilizes a reusable guide bracket (after cleaning/ sterilization by user) and a sterile, single use, disposable cannula.

Substantial Equivalence Table:

Company	**Advance Medical Designs (SUBJECT DEVICE)**	**CIVCO (PREDICATE DEVICE)**	**KOELIS (REFERENCE DEVICE)**	**CIVCO (REFERENCE DEVICE)**	**KOELIS (REFERENCE DEVICE)**
Device Name	Disposable Needle Guides and Grids	Disposable Endocavity Ultrasound Needle/ Biopsy Guide	Disposable Guides KDNG00	VitroPro/ Disposable Endocavity Needle Guide	Reusable Guide KRNG.EL1 KRNG.EL4
510(k) Number	K223689	K970514	K180970	K222052	K141334
Regulation Number	21 CFR 892.1570	21 CFR 892.1570	21 CFR 892.1570	21 CFR 892.1570/ 21 CFR 884.6100	21 CFR 892.1570
Device class	Class II	Class II	Class II	Class II	Class II

Device Common/ Usual Name	Ultrasound Transducer Needle/Instrument Guide	Ultrasound Transducer Needle/Instrument Guide	Ultrasound Transducer Needle/Instrument Guide	Ultrasound Transducer Needle/Instrument Guide	Ultrasound Transducer Needle/Instrument Guide
Device Classification Name	Diagnostic Ultrasonic Transducer Accessories	Diagnostic Ultrasonic Transducer Accessories	Diagnostic Ultrasonic Transducer Accessories	Diagnostic Ultrasonic Transducer Accessories	Diagnostic Ultrasonic Transducer Accessories
Classification Product Code	ITX	ITX	ITX	ITX, MQE	ITX
Indications for Use	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.				
Intended Use	Subject Device, Predicate Device, and References Devices provide fixed guiding of the precise insertion of linear instruments, such as needles through mechanical means with the use of diagnostic ultrasound equipment. The Needle Guides 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. The Needle Guides and Grids are intended to aid clinicians and assistant clinicians, in clinical and hospital settings, to guide linear instruments during any ultrasound procedure that requires the precision use of a needle. Subject, Predicate Device and Reference Devices' indications for use and intended use place *AMD's Disposable Needle Guides and Grids and CIVCO (510k# K970514) /KOELIS (510k# K180970) 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, K222052) provide similar mechanical means for performing needle/ instrument guided procedures with the use of diagnostic ultrasound transducers.				
Design	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	Integrates the mounting bracket and cannula into a single disposable component that attaches externally, over the transducer with a clip-on action.	Plastic guide designed to be clipped on an endocavity ultrasound probe. An entry cone to easily introduce the needle into the tube.	Integrates the mounting bracket and cannula into a single disposable component that attaches externally, over the transducer with a clip-on action.	Inox Guide designed to be clipped on an endocavity ultrasound probe. An entry cone to easily introduce the needle into the tube.

	introduce the needle into the channel				
	Fixation mechanism of the Guide on the probe:				
	A clip to allow the needle guide stability on the transducer and 2 pins for attachment in the notches for the probe	A ring locks the needle guide around the probe thanks to a lateral screw	A clip to allow the needle guide stability on the transducer and 2 pins for attachment in the notches for the probe	A ring locks the needle guide around the probe thanks to a lateral screw	A clip to allow the needle guide stability on the transducer and 2 pins for attachment in the notches for the probe
Materials of Construction	Medical Grade Thermoplastic ABS Polypropylene 304 Stainless Steel All materials have met the requirements of ISO 10993-1 for biocompatibility.	Thermoplastic ABS Polycarbonate 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.	Thermoplastic ABS Polycarbonate 304 Stainless Steel All materials have met the requirements of ISO 10993-1 for biocompatibility.	304 Stainless Steel 3161 Stainless Steel 17/4 PH All materials have met the requirements of ISO 10993-1 for biocompatibility.
Safety/ Biocompatibility	Meets ISO 10993-1 biocompatibility requirements 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,	Meets ISO 10993-1 biocompatibility requirements 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,	Meets ISO 10993-1 biocompatibility requirements 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,	Meets ISO 10993-1 biocompatibility requirements 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,	Meets ISO 10993-1 biocompatibility requirements 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,

	non-hemolytic, and nonpyrogenic	non-hemolytic, and nonpyrogenic	(DOES NOT INCLUDE PYROGEN/ HEMO/ OR ACUTE SYSTEMIC)	(DOES NOT INCLUDE PYROGEN/ HEMO/ OR ACUTE SYSTEMIC)	(DOES NOT INCLUDE PYROGEN/ HEMO/ OR ACUTE SYSTEMIC)
Effectiveness	Subject, Predicate, and all 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. Positive Registration features of the design ensure accurate needle path and placement in relation with the transducer. The exterior shapes of the guides are contoured for the patient comfort with no sharp edges. Advance Medical Designs needle guides and grids devices have the same intended use and their technological characteristics do not raise any different questions of safety or effectiveness, as compared to the legally marketed device. Therefore, the Advance Medical Designs needle guides and grids are substantially equivalent to the legally marketed disposable endocavity needle guide marketed by CIVCO (K972514).				
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Shelf-Life	3 Years	3 Years	3 Years	3 Years	3 Years
Accessories	Ultrasound gel packet and covers.	Ultrasound gel packet and covers.	None provided.	None provided. Intended user to provide cover and guides which are IVF use cleared.	None provided.
Energy Type	None	None	None	None	None
Software	None	None	None	None	None

Design principles of operation are similar between subject device and predicate device(s):

- Placing the Probe Attachment Bracket on the transducer using locating features
- Securing the needle guide onto the transducer by fastening the Attachment Bracket Lock
- Identifying the angle / position to encourage optimal needle trajectory.
- Releasing the Attachment Bracket Lock to remove the needle guide from the transducer.

Subject Device and Predicate Device(s) integrate the mounting bracket and cannula into a single, disposable component that attaches externally, over the transducer; however predicate device uses a clip-on action and subject device uses an Attachment Bracket Lock. The method of maintaining a secure attachment does not change the intended purpose and the devices maintain fixed positions as intended.

Materials of Construction and Manufacturing:

The Advance Medical Designs' Needle Guides, Grids, and Accessories (Kit) have a non-pharmacological, immunological, or metabolic mode of action and both subject and predicate devices have same Shelf-Life's of 3 years.

Predicate Device is fabricated from:

1) Injection molded thermoplastic components, bonded to stainless steel cannula with medical grade adhesive.
2) Injection insert-molded thermoplastic with integral stainless-steel cannula
3) Thermoplastics (ABS and Polycarbonate) and 304 Stainless Steel and packaged in Polyethylene and Tyvek

Subject Device is fabricated from:

1) Injection molded thermoplastic components, but with a stainless-steel attachment.
2) Injection insert- molded thermoplastic with integral stainless-steel cannula
3) Thermoplastics (ABS and Polypropylene) and 304 Stainless Steel and packaged in Polyethylene and Tyvek

Predicate Device and Reference Device (K180970) uses ABS Polycarbonate, and the Subject Device uses ABS Polypropylene.

Chemical Characterization of Polypropylene have been conducted and those studies and results are provided with this application and prove that the materials used to manufacture AMD's Needle Guides and Grids are safe, fully biocompatible, and as effective as Predicate Device and Reference Devices. Materials and manufacturing processing for Predicate Device and Subject Device (including 100 % EtO sterilization w/ SAL 10^{-6}) affects to the healthcare worker and patient via intended use/ indications for use contact of this device have been biologically evaluated using biocompatibility tests for cytotoxicity, irritation, sensitization, pyrogenicity, acute system toxicity, and hemocompatibility.

Sufficient evidence is provided to validate AMD's Claim that subject materials/ device to be non-toxic, non-sensitizing, non-irritating, non-hemolytic, and non-pyrogenic.

Modified Technological Characteristics Deviating from Predicate Device(s) Design, Effectiveness, and Safety:

1. Cannula Guide Channels
    a. Formulation: The guide channel design is based upon the ultrasound system and encourages the needle to align with variable guidelines generated on the system monitor.
    b. Composition: A rigid frame containing evenly spaced through-holes and a connection to the Probe Attachment Bracket.
    c. Functionality: These channels guide a cannula to a set position that aligns with gridlines displayed by the corresponding ultrasound monitor.
2. Probe Attachment Bracket
    a. Formulation: Every bracket is uniquely designed to meet each transducer's specific geometry to maximize the contact surface area and limit the ability for the cannula to shift or rotate about the transducer.
    b. Composition: A mounting structure attached to the Cannula Guide Channels which contains: a surface that fits snugly onto the transducer, a hinge to anchor the Attachment Bracket Lock, a hook to catch the mobile end of the Attachment Bracket Lock.

c. Functionality: This bracket connects the guide channels to the upper side of the transducer in a reliable, inflexible manner such that the channels maintain their position and orientation relative to the transducer. This bracket mates with the bracket lock to physically secure the connection to mitigate the effects of impulse motion or jerk movements.

3. Attachment Bracket Lock
    a. Formulation: This lock is designed to be pulled into tension around the transducer and meets each transducer's specific geometry to achieve adequate holding pressure.
    b. Composition: A semi-rigid arm containing two hooks, one hook for anchoring to the hinge of the Attachment Bracket Lock and another hook on the mobile end to latch onto the hook protruding from the Probe Attachment Bracket.
    c. Functionality: This lock secures the connection between the Probe Attachment Bracket and the transducer. The user wraps this lock around the underside of the transducer and hooks it to one side of the Probe Attachment Bracket.

Summary of Non-Clinical Tests Performed on Subject:

Biocompatibility: The disposable Needle Guides and Grids meet ISO 10993-1 biocompatibility and ASCA- Pilot Biocompatibility Guidance requirements for limited contact duration for surface devices of breached or compromised surface external communicating tissue and indirect blood path.

a. Cytotoxicity – ISO 10993-5
b. Sensitization – ISO 10993-10
c. Irritation – ISO 10993-10
d. Acute Systemic Toxicity– ISO 10993-11
e. Material-Mediated Pyrogenicity- 10993-11 and USP 151
f. Direct and Indirect Hemolysis/Hemocompatibility – ISO 10993-4 and ASTM F756

Summary of Bench Testing Performed on Subject Device:

1) Cover breach and probe damage testing - Water leak testing was performed during Design Input, Design Output, and Design Validation to demonstrate material attachment of needle guide over a cover did not cause damage to cover or probe.

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

3) Needle drag testing Force testing was performed by passing a cannula through the needle guide to ensure binding would not occur and force was less than a 1.5N threshold.

4) Needle path verification testing - Needle guides were tested on test fixtures to ensure needle path falls within the design tolerances specified for the design.

5) Simulated Usability Testing - Simulated use evaluations were performed by customers to ensure the design of the needle guide conforms to the user needs and intended use as well as imaging testing conducted through laboratory evaluations.

Clinical Test Performed:

Clinical tests were not required to demonstrate substantial equivalence.

Conclusions:

The comparisons of the technological and non-clinical performance characteristics indicate Advance Medical Designs, Inc. Disposable Needle Guides & Grids have the same intended use and its technological characteristics do not raise any different questions of safety or effectiveness, as compared to the legally marketed device(s). The improvements made in designs regarding secure attachment prove to be superior and establish the same level, if not greater, of safety and usage. Therefore, AMD's Needle Guides and Grids are substantially equivalent to the legally marketed predicate device disposable endocavity guide marketed by CIVCO. Since the comparison of bench testing to clinical outcomes, documented through images provided, the subject device and predicate device are substantially equivalent. Thus, AMD's (Advance Medical Designs) Needle Guides and Grid's claim demonstrates the device performs comparably to the predicate device and reference devices that are currently marketed for the same intended use.