DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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

October 25, 2017

Re: K163050
Trade/Device Name: Advance Medical Designs, Inc. Sterile Ultrasound Gel
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: MUI
Dated: October 9, 2017
Received: October 10, 2017

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163050

Device Name
Advance Medical Designs, Inc. Sterile Ultrasound Gel

Indications for Use *(Describe)*
Advance Medical Designs, Inc. Sterile Ultrasound Gel is intended for general us as a sterile transmission media for acoustically coupling a transducer to a human body surface during external diagnostic ultrasound imaging procedures. It is placed on the patient's intact skin prior to initiating an ultrasound examination. It is indicated for prescription use only.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
Advance Medical Designs, Inc. Sterile Ultrasound Gel
Common Name: Ultrasound Gel
Product Code: MUI
Device classification: Class II
21 CFR 892.1570
Traditional 510(k) Submission
October 20, 2017

General Information

- 510(k) owner's name:
  Advance Medical Designs, Inc.
  1241 Atlanta Industrial Drive
  Marietta, GA 30066 USA
  (770) 422-3125

- Contact person:
  David Mackie, QA/RA Manager at Advance Medical Designs, Inc.
  (770) 422-3125 ext. 244
  mackied@advmeddes.com

- Prepared on October 20, 2017

Device Name

- Trade name:
  Advance Medical Designs, Inc. Sterile Ultrasound Gel

- Common Name:
  Ultrasound Gel

- Classified Name:
  Diagnostic ultrasonic transducer/acoustic gel
  (21 CFR 892.1570, Product code MUI)

Predicate Device

- Konix® Ultrasound Gel (K101952)

Device Description

Advance Medical Designs, Inc. Sterile Ultrasound Gel consists of deionized water, glycerin, butylene glycol, glyceryl acrylate/acrylic acid copolymer, propylene glycol, carbomer, phenoxyethanol, cellulose gum, sodium hydroxide, hydroxyethlcellulose, ethylhexylglycerin. It is a type of conductive medium (i.e.) scanning gel used in ultrasound therapeutic and diagnostic imaging techniques. A scanning

gel acts as a couplant that provides an acoustic pathway between transducer and the intact skin. In addition, the gel eliminates air (a disruptive influence) from the interface and adapts to the contours of the probe to the intact skin.

The major characteristics of Advance Medical Designs, Inc. Sterile Ultrasound Gel:

- Hypoallergenic, non-irritating
- Water soluble, non-staining and easily cleanable
- Free from formaldehyde and salt
- Does not contain oil or fatty matter
- No toxic effects
- Vacuum treated production
- Produced as a completely harmless material
- Does not damage the probe
- Does not contain air bubbles

Intended Use

Advance Medical Designs, Inc. Sterile Ultrasound Gel is intended for general use as a sterile transmission media for acoustically coupling a transducer to a human body surface during external therapeutic and diagnostic ultrasound imaging procedures. It is placed on the patient's intact skin prior to initiating an ultrasound examination. It is indicated for prescription use only.

Technological Characteristics:

Advance Medical Designs, Inc. Sterile Ultrasound Gel has substantially the same technological characteristics as the predicate device.

Conclusions

The comparisons of the technological and non-clinical performance characteristics indicate that Advance Medical Designs, Inc. Sterile Ultrasound Gel is almost identical to the predicate device and therefore substantially equivalent to it and other coupling gels commonly used in the United States today.