July 1, 2020

Allwin Medical Devices, Inc.
Digish Mehta
Business Development Manager
3305 East Miraloma Avenue, Suite 176
Anaheim, CA 92806

Re: K200248
Trade/Device Name: Allwin Embryo Transfer Catheters (ETC), Allwin ETC Stylets and Soft Obturators
Regulation Number: 21 CFR§ 884.6110
Regulation Name: Assisted Reproduction Catheters
Regulatory Class: II
Product Code: MQF
Dated: June 1, 2020
Received: June 1, 2020

Dear Digish Mehta:

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,

Monica D. Garcia, Ph.D.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200248

Device Name
Allwin Embryo Transfer Catheters (ETC), Allwin ETC Stylets and Soft Obturators

Indications for Use *(Describe)*

Allwin ETC include the following models: Embryo Trans, Echo Trans, Twinkle Embryo Trans, Bulb Trans Ultra, Bulb Trans Star, Pro Embryo Trans, Pro Echo Trans, and Twinkle Pro Embryo Trans Embryo Transfer Catheter.

Allwin Embryo Transfer Catheters are used to introduce in vitro fertilized (IVF) embryos into the uterine cavity. Allwin Embryo Transfer Catheters (Pro Embryo Trans, Pro Echo Trans, Twinkle Pro Embryo Trans, and Bulb Trans Star ETC) include stylets or soft obturators intended to assist in uterine access of the guide catheter during an embryo transfer procedure.

Allwin ETC Stylets and Soft Obturators include the following models: Stylet For Embryo Trans / Echo Trans / Twinkle Embryo Trans, Stylet For Pro Embryo Trans / Pro Echo Trans / Twinkle Pro Embryo Trans, Stylet for Bulb Trans Ultra / Bulb Trans Star, Soft Obturator For Pro Embryo Trans / Pro Echo Trans / Twinkle Pro Embryo Trans Embryo Transfer Catheter.

Allwin Stylets and Soft Obturators are intended to be used with Allwin Embryo Transfer Catheters to assist in uterine access of the guide catheter during an embryo transfer procedure.

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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