January 25, 2018

Medinol, Ltd.
% H. Semih Oktay
President
CardioMed Device Consultants
5523 Research Park Drive
Suite 205
Baltimore, Maryland 21228

Re: K173581
Trade/Device Name: Gallant PTCA Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: November 16, 2017
Received: November 20, 2017

Dear H. Semih Oktay:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Kenneth J. Cavanaugh -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K173581

Device Name
Gallant PTCA Dilatation Catheter

Indications for Use *(Describe)*
The Gallant PTCA Dilatation Catheter is indicated for:
• Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion;
• Post-deployment stent expansion.

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 -- K173581
Medinol LTD's Gallant PTCA Catheter

Submitter's Name and Address	Medinol Ltd. Kiryat Atidim, Building 8, Tel Aviv 6158101, Israel
Contact Name and Information	Marina Tikhonov Demishtein VP Regulatory Affairs Phone: +972 3 7679000 Fax: + 972 3 648 2310 marinat@medinol.com
Date Prepared	November 16 2017
Proprietary Name(s)	Gallant PTCA Dilatation Catheter
Common Name	Catheters, transluminal coronary angioplasty, percutaneous
Product Code	**LOX**
Classification	Class II, 21 CFR Part 870.5100
Predicate Devices	NC Gallant PTCA Dilatation Catheter (K162434)
Reference Devices	Trek & Mini-Trek, Abbott (K103110)
Device Description	The Gallant is a sterile, single-use, intravascular medical device. The Gallant is a combination of single lumen and dual lumen catheter comprising an expandable semi-compliant (SC) coronary balloon on a rapid exchange (RX) catheter.
Intended Use of Device	The Gallant PTCA Dilatation Catheter is intended for the dilatation of stenosis in coronary arteries or bypass grafts.
Indications for Use	The Gallant PTCA Dilatation Catheter is indicated for: • Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion; • Post-deployment stent expansion.
Comparison of Technological Characteristics	The Gallant PTCA Dilatation Catheter incorporates substantially equivalent device design, fundamental technology, manufacturing processes, sterilization and intended use as those featured in the predicate device: NC Gallant PTCA Dilatation Catheter (K162434). Minor differences identified between the Gallant and it's predicate device were evaluated in the frame of performance testing as described below.

Performance Data

The Gallant PTCA Dilatation Catheter was subjected to testing according to the requirements of Guidance for Industry and FDA Staff – *Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, September 8, 2010.

Bench testing, pre-clinical studies, biocompatibility testing and chemical characterization testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing and, therefore, the Gallant may be considered substantially equivalent to the predicate device.

The following biocompatibility tests were completed on the Gallant PTCA Dilatation Catheter:

Cytotoxicity	Sensitization
Intracutaneous Toxicity	Material Mediated Pyrogenicity
In Vitro Hemolysis	SC5b-9 Complement Activation Assay
Chemical Characterization	
The following in-vitro performance tests were completed on the Gallant PTCA Catheter:	
Visual and Handling Performance	Dimensional Verification
Crossing Profile	Simulated Use
Kissing Balloon Technique (KBT)	Balloon Rated Burst Pressure
Balloon Fatigue (Repeat Balloon Inflations)	Balloon Diameter vs. Balloon Pressure (Compliance), Balloon Diameter at NIP, Balloon Diameter at RBP, Balloon Working Length, Balloon Non-uniformity Markers Positioning,
Catheter Bond Strength	Tip Pull Test
Flexibility and Kink Resistance	Torque Strength
Catheter Radiopacity	Particulate Evaluation
Coating Integrity	Balloon Rated Burst Pressure (in Stent)
Balloon Fatigue (Repeat Balloon Inflations; in Stent)	Catheter corrosion resistance
Packaging Integrity	Environmental & Shipping & Accelerated Shelf-Life

	The following in-vitro performance tests were completed on the Gallant PTCA Catheter:
	GLP Acute Performance Study of Novel Gallant PTCA Balloons in a Porcine Model
Conclusion	Based on the indications for use, technological characteristics, safety and performance testing, the Gallant PTCA Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the predicate device.