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**December 18, 1995**

**Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate BLVD.  
Rockville, Maryland 20850**

**The Safe Medical Device Act Summary**

**RE: Premarket Notification for  
Gyro Tip EP Catheter**

**This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.**

**In accordance with Section 510(K) of the Federal Food, Drug and Cosmetic Act, notification is hereby made of the intention of the Cardiac Assist Devices, Inc. to market the following device:**

1.   **Device Name:** Gyro Tip EP Catheter  
      **Classification Name:** Electrode Recording Catheter  
      **Common Name:** Deflectable Tip Recording Catheter  
      **Trade Name:** Gyro Tip EP Catheter  
  
      **Intended Use:** Monitor and record intra-cardiac electrical activities
  
2.   **Cardiac Assist Devices, Inc. has submitted form FDA-2891 (Initial Registration of Medical Device Establishment) for its manufacturing facility located at 11000 Cedar Ave. Suite 451, Cleveland, Ohio 44106-3052, to FDA.**
  
3.   **Classification:** Electrode Recording Catheters have been officially classified as CLASS II as described in 21CFR870.1280

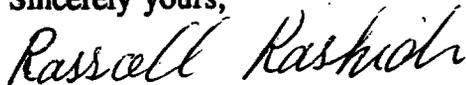
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**The Safe Medical Device Act Summary (continue)**

4. Performance Standards: None Established
  
5. Draft Labelling of the Gyro Tip EP Catheter is presented in Section 9 of this document. This Draft Labeling includes: Direction for Use, Indications, Cautions, Description, Warnings and Precautions.
  
6. Substantial Equivalence: The Gyro Tip EP Catheter is **substantially equivalent** to Bard Dynamic Tip Catheter (K912213), Bard Tip Deflecting Catheter (K904080), Bard Tip Deflecting Electrode Catheter (K891908), and Steerocath (K900765). Section 4 of this document contains a detailed statement of substantial equivalence.
  
7. Section 1 (Executive Summary) of this document is a more comprehensive summary statement that includes additional information regarding the material biocompatibility, physical characteristics, results of electrical and mechanical tests and a general description of the Gyro Tip EP Catheter.

If you have any questions or require any additional information regarding the content of this document, please call me at (216) 791-2234 or fax to: (216) 281-4639.

Sincerely yours,



Rassoll Rashidi, BME.  
President