AUG 26 2005 K050889 page 1 of 2

EXHIBIT 2
510(k) Summary

CRS Medical Diagnostics, Inc.
662 Capitol Drive
Pewaukee Wisconsin 53072
Tel 262-264-0047
Fax 262-264-0051

August 19, 2005

Contact: Robert S. Brewer, Chairman of the Board

1. **Identification of the Device:**
   Proprietary-Trade Name: CRS Endoluminal Brush
   Classification Names: Catheter, intravascular, therapeutic, long-term greater than 30 days, product code LJS
   Common/Usual Name: Endoluminal Brush

2. **Equivalent legally marketed devices** The CRS Endoluminal Brush is IDENTICAL to the FAS Endoluminal Brush, K993614

3. **Indications for Use (intended use)** The CRS Endoluminal Brush is intended to collect a biofilm or fibrin sample, which is suitable for microbiological analysis, from the inner lumen surface of an in-dwelling central venous catheter

4. **Description of the Device:** The CRS Endoluminal Brush product line is an accessory to central venous catheters. Each single use Endoluminal Brush kit contains 2 pairs of latex free gloves, 1- 70% isopropyl alcohol cleaning agent, 1 fibrin brush in transport bag, 1- 10 cc syringe, 2 patient labels, 1 medical drape, 1 over wrap, and Instructions for Use. The brush consists of nylon bristles wound into a flexible stainless steel wire, which is further wound into a tubular, metal, rigid handle. The Brush is enclosed within a plastic sheath that is heat sealed at the distal end and is attached to a standard luer lock at its proximal end. The luer lock fitting complies with catheter manufacturers' requirement that only luer-lock connections be used with catheters. The various CRS Endoluminal Brush products defined by the product codes differ mainly in the length of the flexible wire and the diameter of the Brush bristles.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and clinical testing indicates that the new device is as safe and effective as the predicate devices.

6. **Substantial Equivalence Chart,** CRS Endoluminal Brush

Characteristic	Predicate FAS Endoluminal Brush K993614	CRS Endoluminal Brush K050889
Intended Use:	Intended to collect a biofilm or fibrin sample, which is suitable for microbiological analysis, from the inner lumen surface of an in-dwelling central venous catheter	Same
Instructions for Use:	Provided with illustrations	Same
Target Population:	Patients with indwelling catheters.	Same
Anatomical Size:	Patient catheter	Same
Area of Use:	Hospital	Same
Design:	Per patent 5,405,755	Same
Standards Met:	ANSI/AAMI Biocompatibility; Non-pyrogenic	Same
Materials:	Nylon bristles wound into a stainless steel flexible wire	Same
Supplied items:	Measuring tape, patient drape, instructions for use, wire clippers, specimen container with cap, patient identification label	2 Pair Latex-free Gloves Endoluminal Brush In Transparent Sheath Cleaning Agent 1 10cc Syringe 1 Overwrap Drape 1 Medical Drape 2 Patient Identification Labels Package insert
Sterility:	Provided packaged and sterile, Gamma Single Use Only	Provided packaged and sterile, EO Single Use Only
Electrical Safety:	N/A	N/A
Chemical Safety:	N/A	N/A
Energy Used and/or Delivered:	N/A	N/A

7. **Conclusion**
The CRS Endoluminal Brush does not raise any issues of safety or effectiveness compared to the predicate device because it is in fact the predicate device..

Indications for Use

510(k) Number K050889

Device Name: CRS Endoluminal Brush

Indications For Use:

The CRS Endoluminal Brush is intended to collect a biofilm or fibrin sample, which is suitable for microbiological analysis, from the inner lumen surface of an in-dwelling central venous catheter

Prescription Use X AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 2005

CRS Medical Diagnostics, Incorporated
C/O Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K050889
Trade/Device Name: CRS Endoluminal Brush
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-term Intravascular catheter
Regulatory Class: II
Product Code: LJS
Dated: June 22, 2005
Received: June 27, 2005

Dear Mr. Kamm:

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 aga\inst misbranding and adulteration.

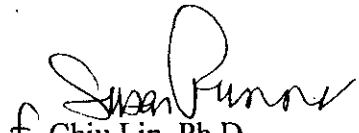
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050889

Indications for Use

510(k) Number K050889

Device Name: CRS Endoluminal Brush

Indications For Use:

The CRS Endoluminal Brush is intended to collect a biofilm or fibrin sample, which is suitable for microbiological analysis, from the inner lumen surface of an in-dwelling central venous catheter

Prescription Use X AND/OR Over-The-Counter Use ___.
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K050889