Exhibit #1

K120852

JUN - 6 2012

510(K) SUMMARY

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.

Date Prepared: March 16, 2012

1. **Applicant:**

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Kerox Ltd.
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Hungary

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2. **Submitter:**

Mr. Sangram Yadav
Official Correspondent for
Kerox Ltd
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

TEL: 516-482-9001
FAX: 516-482-0186

EMAIL:sangram@mdiconsultants.com

3. **Name of the Device:**

Zircostar (zirconia blanks)

4. **Common or Usual Name and Classification:**

Porcelain powder for clinical use.
Regulation number: 872.6660
Product Code EIH

5. **Predicate Device Information**:

Dental Direct DD Bio Z, DD Bio Z-transpa
510k number: (k093748)

6. **Device Description** :

Zirconia Blanks are dental materials (semi finished products) made of pre-sintered zirconium dioxide for milled production of crowns and bridges frameworks on commercial CAD/CAM systems or hand operated copy-milling machines, with outstanding biocompatibility and high resistance against tension and pressure.

In its pre-sintered condition the product is excellently suitable for preparing dental prostheses(crowns, bridges, superstructures, inlays and olays) produced by manual and machine milling technique.

7. **Intended Use**

Zirconia Blanks are indicated for crowns, multi-unit bridges and inlay bridges Applications include both anterior and posterior bridges.

8. **Comparison to Predicate Devices:**
The Zircostar (Zirconia blank) is substantially equivalent to the Dental Direct DD Bio Z, DD Bio Z-transpa the predicate device in intended use, operation, safety and function.

9. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Mechanical testing, Material analysis and biocompatibility tests were performed by third party laboratories. The device passed all tests.

10. Clinical Testing:

Kerox Ltd. did not conduct clinical tests to determine substantial equivalence.

11. Non Clinical Testing:

Kerox dental did not conduct, nor rely upon, clinical tests to determine substantial equivalence. Non-clinical testing was performed in order to validate the design against the company's specified design requirements, and to assure conformance with the following voluntary design standard: ISO 6872:2008.

Risk Management:
The device has been designed to either completely eliminate or mitigate known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous
Application of a risk management program according to ISO 14971 "Medical devices - Application of risk management to medical devices".

Technological characteristics:
The technological characteristics between the predicate and proposed devices are identical. There is no difference in fundamental scientific technology. They have the same intended use.

12. Conclusion:

Kerox Ltd believes that Zircostar (Zirconia blank) is as safe and effective as the predicate device when used as instructed by knowledgeable and trained personnel, and are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Kerox Limited
C/O Mr. Sangram Yadav
Official Correspondent
MDI Consultants, Incorporated
55 Northern Blvd., Suite 200
Great Neck, New York 11021

JUN - 6 2012

Re: K120852
Trade/Device Names: Zircostar Zirconia Blanks
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: May 30, 2012
Received: May 31, 2012

Dear Mr. Yadav:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120852

Device Name: Zirconia Blanks (Zircostar)

Indications for Use:

Zirconia Blanks are indicated for crowns, multi-unit bridges and inlay bridges. Applications include both anterior and posterior bridges.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Per 21CFR 801 Subpart D) (21CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K120852