EXHIBIT #1

SEP 1 2 2008

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.

The assigned 510(k) number is: K081694

1. **Submitter's Identification:**

Company Name:	DXM CO. LTD.
Address:	1016, ILsantechnotown Bldg., 1141-1, Baekseok-dong, ILsan-gu Goyang-si, Gyeonggi-do, KOREA
Tel:	**011 82 31 909 8275**
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Date Prepared: June 16, 2008

2. **Name of the Device:** Denjector

3. **Common or Usual Name:** Syringe, Cartridge

4. **Classification:** Class II, 21 CFR 872.6670

5. **Predicate Device Information**: CCS; computer controlled syringe distributed by DENTSPLY Midwest Professional Ltd., K983105

6. **Device Description** :

Denjector is a gun type electronic dental anesthetic cartridge syringe. This device is used with injectable local anesthetics packaged in cartridge form. The device consists of: Injector gun, battery, battery charger stand, DC adapter for battery charger stand, Cartridge holder and Cartridge pushing/pulling pin. Standard needles may be used with the device.

7. **Intended Use**

Indicated for the use of local anesthetics for infiltration and nerve block anesthesia administered prior to, or in conjunction with dental procedures.

8. **Comparison to Predicate Devices:**

The Denjector is substantially identical to the predicate in intended use, operation, safety and function. The main difference between the two devices is that the predicate is software controlled and the Denjector is motor controlled.

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

Testing information demonstrating safety and effectiveness of the Denjector in the intended environment of use is supported by testing that was conducted in accordance with EN 60601-1, EN 61000-3-2 and EN 61000-3-3.

None of the testing demonstrated any design characteristics that violated the requirements of the standards or resulted in any safety hazards.

10. **Discussion of Clinical Tests Performed:**

Clinical testing was not conducted.

11. **Conclusions:**

Based on the information provided in this submission we conclude that the Denjector is substantially equivalent to the predicate and is safe and effective for it's intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 2 2008

DXM Company, Limited
C/O Ms. Maria Griffin
Mdi Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K081694
Trade/Device Name: Denjector
Regulation Number: 21 CFR 872.6770
Regulation Name: Cartridge Syringe
Regulatory Class: II
Product Code: EJI
Dated: June 16, 2008
Received: June 17, 2008

Dear Ms. Griffin:

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division 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): K081694

Device Name: Denjector

Indications For Use:

Indicated for the use of local anesthetics for infiltration and nerve block anesthesia administered prior to, or in conjunction with dental procedures.

Prescription Use __X__ (Per 21CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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: K081694