MAR 2 2 2005



K043033

# 510 (K) SUMMARY

**Date of Summary**
October 28, 2004

**Product Name:**
Fluid Filled Teether

**Manufacturer:**
Global Treasures Industrial Ltd.
Nan Fung Ind. Cit
18 Tin Hau Road
Tuen Mun N.T. , HK

**Sponsor**
Global Treasures, Industrial, Inc.
Nan Fung Ind. Cit
18 Tin Hau Road
Tuen Mun, N.T., HK

**Correspondent:**
Fran White
MDC Associates
163 Cabot Street
Beverly, MA 01915

**Substantially Equivalent Device:**
Fluid Filled Teether
Manufactured by: Royal King Products Company Limited
K031094

**Product Description:**
Fluid Filled Teether

**Intended Use:**
The intended use of the fluid filled teether is to help to relieve the teething discomfort of teething infants by providing a cool soothing effect.

The Global Fluid Filled Teether is intended for over-the-counter use.

**Conclusion:**
The Global Fluid Filled Teether is substantially equivalent to the fluid filled teether manufactured by Royal King Infant Products Company Limited (K031094).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2005

Global Treasures Industrial Limited
C/O Ms. Fran White
President
MDC Associates
163 Cabot Street
Beverly, Massachusetts 01915

Re: K043033
Trade/Device Name: Fluid Filled Teether
Regulation Number: 872.5550
Regulation Name: Teething Ring
Regulatory Class: II
Product Code: KKO
Dated: February 21, 2005
Received: February 23, 2005

Dear Ms. White:

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.

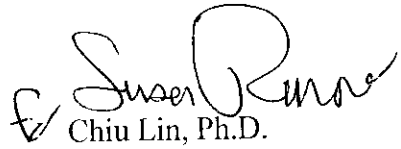
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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

# 510k Submission
# Global Treasures
# Fluid Filled Teether



**510(k) Number:** K043033

**Device Name:** **Fluid Filled Teether**

**Indication for Use:**

The intended use of the fluid filled teether is to help to relieve the teething discomfort of teething infants by providing a cool soothing effect.

The Global Fluid Filled Teether is intended for over-the-counter use.

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

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**Prescription Use**_____
**(Per 21 CFR 801.109)**

**OR**

**Over the Counter Use** _____
**(Optional Format 1-2-96)**

Susan Runner

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

510(k) Number K043033