K034017

## SECTION 14: SUMMARY OF SAFETY AND EFFECTIVENESS

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

### 14.1 SUBMITTER INFORMATION

| | |
|---|---|
| a. Company Name: | Vibe 2000 |
| b. Company Address: | 511 Iguera Drive<br>Oxnard, CA 93030 |
| c. Company Phone: | (805) 377-2709 |
| d. Contact Person: | Mario Gonzalez |
| e. Date Summary Prepared: | December 19, 2003 |

### 14.2. DEVICE IDENTIFICATION

| | |
|---|---|
| a. Trade/Proprietary Name: | JeJe Teether |
| b. Classification Name: | Non-fluid Filled Teething Rings<br>21 CFR 872.5550 |

### 14.3 IDENTIFICATION OF PREDICATE DEVICES

The JeJe Teether is substantially equivalent to other Class I non-fluid filled teething rings that are in commercial distribution.

### 14.4 DEVICE DESCRIPTION

The JeJe Teether is a vibrating teething ring that is designed for infants to play with and chew on. The device is battery-operated and vibrates when activated. The JeJe Teether is constructed of ABS resin plastic material and is circular in shape.

## 14.5 SUBSTANTIAL EQUIVALENCE

The JeJe Teether is substantially equivalent to other non-fluid filled teething rings in commercial distribution. The JeJe Teether has the added feature of being able to vibrate when activated.

The fundamental technical characteristics of the JeJe Teether are similar to those of other commercially available teething rings. The JeJe Teether is equivalent to other teething rings in design, functionality, materials and intended use.

## 14.6 INTENDED USE

The JeJe Teether is intended for infants to play with and chew on, and to help soothe teething infants.

## 14.7 TECHNOLOGICAL CHARACTERISTICS

The JeJe Teether was subjected to several performance evaluations to verify that the device meets industry standards for consumer toy safety. The JeJe Teether was found to be acceptable in all applicable categories including flammability and mechanical hazards. The product was found to be PVC free.

## 14.8 510(K) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2004

Vibe 2000
C/O Ms. Carol White
President
Patterson Consulting Group, Incorporated
21911 Erie Lane
Lake Forest, California 93030

Re: K034017
Trade/Device Name: JeJe Teether
Regulation Number: 872.5550
Regulation Name: Teething Ring
Regulatory Class: I
Product Code: MEF
Dated: July 29, 2004
Received: August 3, 2004

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/dsma/dsmamain.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

# INDICATION FOR USE

510(k) Number: To Be Assigned By FDA K034017

Device Name: JeJe Teether

Indications for Use: The JeJe Teether is intended for infants to play with and chew on, and to help soothe teething infants.

(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: K034017

Prescription Use __ _____ OR Over-The-Counter Use ✓

(Per 21 CFR 801.109)