EXHIBIT #1

DEC - 9 1999

510(K) SUMMARY

K992995

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:_____.

1. Submitter's Identification:

AGAPlastic Ind. Com. Ltda.
Rua Conde de Agrolongo,
362 Penha
21020-190 Rio De Janeiro-RJ
BRAZIL

Date Summary Prepared: August 1999

Contact: Mr. Cezar Reis,
Tel: 55 21 260-5753
Fax: 55 21 266-5130

2. Name of the Device:

Aromatic and Flavored Tongue Depressor

3. Predicate Device Information:

The Torrent Corporation, Tongue Depressor, K# 842461

4. Device Description:

The Aromatic and Flavored Tongue Depressor is for medical use which is comprised of a non-toxic thermoplastic material and an aromatic sweetener. The device is molded through a process of injection molding originating an article of vibrant colors, with taste and smell, 8 to 20 cm. long; 1 to 4 cm wide and 0.1 to 0.3 cm thick.

5. Intended Use:

The Aromatic and Flavored Tongue Depressor is intended to displace the tongue to facilitate examination of the surrounding organs.

6. Comparison to Predicate Devices:

Company	Device	Material	Size(s)	Intended Use
The Torrent Corp.	Tongue Depressor	wood	similar	same
AGAPlastic	Tongue Depressor	polypropylene	similar	same

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

Testing information demonstrating safety and effectiveness of the Aromatic and Flavored in the intended environment of use is supported by testing that was conducted for the plastic, pigments/colors, aroma and flavor/taste.

Material Testing Certifications were supplied with the 510(k) submission.

8. Discussion of Clinical Tests Performed:

A biocompatibility assessment was conducted for patient-contacting materials, and biocompatibility testing results revealed passing data.

9. Conclusions:

Based on the similarities of the two devices and supporting test data for both the polypropylene and the additives, the Aromatic and Flavored Tongue Depressor is as safe and effective as the predicate device. Furthermore, it does not raise any new questions regarding safety and effectiveness from the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 9 1999

AGA Plastic Incorporated
Ms. Susan D. Goldstein-Falk
Official Correspondent
for AGA Plastic Incorporated
c/o MDI Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, NY 11021

Re: K992995
Trade Name: Aromatic and Flavored Tongue Depressor
Regulatory Class: I
Product Code: FMA
Dated: November 16, 1999
Received: November 19, 1999

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992995

Device Name Aromatic and Flavored Tongue Depressor

Indications For Use:

The Aromatic and Flavored Tongue Depressor is intended to displace the tongue to facilitate examination of the surrounding organs. They are available in the following colors: Yellow, blue, orange, magenta, pink, green and red.

(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)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992995