K101348

**Exhibit 1**

## 510(K) SUMMARY

APR 2 9 2011

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 Industria e Comercie Ltda.**
Rue Cuba, 353
Rio de Janeiro
RJ Brasil
CEP:210-160

Tel.: 55 21 2573 0969
Fax.: 55 21 2573 2336

Date Summary Prepared: November 10, 2010

**2. Name of the Device:**

Proprietary name: Agachamber Spacer with mask

**3. Classification:** 21 CFR 868.5630, Class II
**Product Code:** NVP

**4. Common or Usual Name:**

Common name: Spacer
Classification name: Nebulizer (Direct Patient Interface)

**5. Predicate Device Information:**

**a) Legally Marketed Equivalent Device:**

Aerochamber Plus Anti-Static Valved Hold
Manufactured by Trudell Medical International with 510k Number: K070674.
Product code: NVP

**6. AgaChamber Spacer Description:**

AgaChamber Spacer is composed of a conical chamber with openings on both of its sides, where in one of these opening there is an attached base

with an orifice into which the medication dose is inserted and the Metered Dose Inhaler dispenses the medication. On the other side, there is a nozzle which holds the mask, which the patient will fit over his/her nose and mouth so that the medication can be inhaled. The device has been developed for use, with or without mask.

The percentage of the drug dose delivered into the chamber is totally dependent on the Metered Dose Inhaler's pressure and quantity of metered doses the healthcare provider prescribes. Another point that should be clear is that, AgaChamber is a passive device and its main function is to provide a space extension between the Metered Dose Inhaler and the patient's nose and mouth in order to facilitate the inhalation of the medication.

- AgaChamber is composed of wrought plastic parts and assembled together by a process of thermoplastic injection.
- IMPORTANT NOTE: AGACHAMBER SPACER IS LATEX FREE

**7. <u>Intended Use:</u>**

The AgaChamber Spacer is intended to be used by patients, who are under the care or treatment of a licensed healthcare provider or physician. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers, prescribed by a physician or healthcare professional. The device has been developed for use, with or without mask, in accordance with necessity and medical orientation. The intended environments for use include home, hospitals and clinics.

**8. <u>Technological Characteristics:</u>**

AgaChamber's techonological characteristics are similar to the legally marketed equivalent, AeroChamber, from its basic material compositions (please see images below), to its function, as well as its intended use, which is classified as; "to facilitate the use of an inhaler and to improve the passage of medication to the lungs".

AgaChamber has been developed for adult and child use, with or without the use of the mask, in accordance with necessity and medical orientation. AgaChamber, likewise legally marketed AeroChamber, is to be used according to a doctor's orientation.
There are no distinctions in the usage of AgaChamber and AeroChamber, both are intended to maximize the efficacy of inhaling medications that need to be delivered to the lungs to treat respiratory ailments. Both have the same overall structure and carry on the same delivery process,

therefore both serve for the same purposes. (Please see images below.)

***Aerochamber***


***AgaChamber***


**9. Performance Data:**

**Non-clinical**: Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the Agachamber Spacer with mask with respect to the predicate device.

Third party testing was performed including biocompatibility testing per ISO 10993-10:2002/AM:2006 and ISO10993-5:2009 as well as Aerosol Performance Testing per the FDA Guidance document "Reviewer Guidance for Nebulizers, MDI's, Spacers and Actuators".

The device passed all of the tests based on pre-determined Pass/Fail criteria.

**10. Conclusions:**

The data from the biocompatibility and non clinical tests show that the Agachamber Spacer with mask is as safe and effective as the legally marketed predicate device.

Therefore we conclude that the Agachamber Spacer with mask is substantially equivalent to the predicate device.

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

Agalastic Industria e Comercie Ltda.
C/O Ms. Maria F. Griffin
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

APR 2 9 2011

Re: K101348
Trade/Device Name: AgaChamber Spacer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: NVP
Dated: April 21, 2011
Received: April 22, 2011

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. 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):**

**Device Name: AgaChamber Spacer**

**Indications For Use:**

The AgaChamber Spacer is intended to be used by patients, who are under the care or treatment of a licensed healthcare provider or physician. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers, prescribed by a physician or healthcare professional. The device has been developed for use, with or without mask, in accordance with necessity and medical orientation. The intended environments for use include home, hospitals and clinics.

**Prescription Use __X__** **Over-The Counter Use_____**

**(Per 21 CFR 801 Subpart D)** **OR** **(21 CFR 807 Subpart C)**

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

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

Division Sign-Off)
)ivision of Anesthesiology, General Hospital
:fection Control, Dental Devices

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