SEP 30 2005

EXHIBIT C

K042564
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HEMOR~RITE Cryotherapy

510 (k) Summary

OWNER:

FAMA Holdings International Corporation
4613 N University Drive
Suite 252
Coral Springs, Florida 33067
Telephone: (866) 436-6748
Fax: (305) 402-2253

CONTACT PERSON:

Christine M. Humphrey, Esq.
(786)245-0440

DATE PREPARED:

September 27, 2005

1. Device Name

Proprietary Name: Hemor~Rite Cryotherapy
Common/Usual Name: Hemorrhoid Device
Device Classification: Device, Thermal, Hemorrhoids (LKX)

2. Predicate Device:

Applicant: Cryotherapy Pain Relief Products, Inc.
Proprietary Name: ANUICE
510(k): K981428

3. **Device Description and Indications For Use**:

DESCRIPTION:

Hemor~Rite Cryotherapy is an anatomically designed device for applying cold therapy (Cryotherapy) directly to the swollen hemorrhoidal veins of external hemorrhoids and the internal hemorrhoids within the rectal cavity. The direct application of cold provides prompt relief of itching, pain, and swelling. In addition, Hemor~Rite Cryotherapy is beneficial for the treatment of anal and perianal fissures due to the vasoconstriction and analgesia properties of the device. Hemor~Rite Cryotherapy has been designed taking the following factors into consideration: human anatomy and the medical concepts for treating the ailment.

TREATMENT PERIOD:

Use the Hemor~Rite Cryotherapy device for a minimum of four times daily for the first week of treatment. After the first week, use the Hemor~Rite Cryotherapy device at least twice a day until the symptoms disappear. Product reusable for a maximum of six months after first application.
Note: Please allow a minimum of two hours between each treatment.

INSTRUCTIONS FOR USE TO TREAT INTERNAL HEMORRHOIDS:

1. Insert the Hemor~Rite Cryotherapy device in its case and place in the freezer for a minimum of two (2) hours.

2. After the minimum time has elapsed, remove the Hemor~Rite Cryotherapy device from its case. Holding it by the base, apply several drops of lubricant to the tip and allow the drops to drip down the neck of the Hemor~Rite Cryotherapy Device.

3. Lie on one side, with one leg extended and the other leg bent towards the abdomen (See Image 1). Take the Hemor~Rite Cryotherapy device by the base, holding it with the wider end pointing towards the front (towards the genitals) and the narrower end toward the back (See Image 3). Insert the lubricated device slowly and smoothly into the anal canal until it is completely inserted.

4. Use the Hemor~Rite Cryotherapy device for 6 to 8 minutes, or until it reaches body temperature, for a maximum of 10 minutes.

5. Remove the Hemor~Rite Cryotherapy device slowly and smoothly. Wash it with soap and warm water or any external antiseptic. Remove excess moisture with a paper towel and place the dry device in its case.

6. Return the Hemor~Rite Cryotherapy device to the freezer and follow the above procedure for each use.

WARNING: This device should be discarded if the user detects any cracks or breaks in the device. Should Hemor~Rite Cryotherapy device crack or break and the coolant comes in contact with the skin rinse with water. If the coolant comes into contact with eyes flush with plenty of water.

WARNINGS:

- The Hemor~Rite Cryotherapy device is for personal anal use only and should be kept in its sanitary case when not in use.

- Do not introduce the Hemor~Rite Cryotherapy device in to the rectal canal without lubrication.

- The cooling material contained in the Hemor~Rite Cryotherapy device may be toxic.

- Only the neck of the Hemor~Rite Cryotherapy device should be inserted into the rectal canal.

HEMOR~RITE
Cryotherapy

- For advanced hemorrhoidal conditions, grades 3 and 4, the Hemor~Rite Cryotherapy device should be used for external hemorrhoidal treatment only. Once the swelling and the condition of the hemorrhoids have improved, you may then proceed to the internal hemorrhoidal treatment.
  Third degree (3) hemorrhoids prolapse with defecation but recede only by manual reduction. Fourth degree (4) hemorrhoids are permanently prolapsed and cannot be reduced into the anal canal.
- Do not use if you have an elevated reaction to extreme cold or Cryotherapy.
- Keep out of reach of children.
- Hemor~Rite Cryotherapy is a drug free treatment. No prescription needed.
- Hemor~Rite Cryotherapy device should not be taken apart.
- Hemor~Rite Cryotherapy device should not be used in pregnant women or children without prior approval of a physician.
- Hemor~Rite Cryotherapy device is flammable once ignited, may burn rapidly.
- Stop Hemor~Rite Cryotherapy treatment and consult a physician if symptoms continue past seven (7) days or bleeding continues.

INSTRUCTIONS FOR USE TO TREAT EXTERNAL HEMORRHOIDS:

1. Insert the Hemor~Rite Cryotherapy device in its case and place in the freezer for a minimum of two (2) hours.

2. After the minimum time has elapsed, remove the Hemor~Rite Cryotherapy device from its case.

3. Lie on one side, with one leg extended and the other leg bent towards the abdomen (See Image 2). Take the Hemor~Rite Cryotherapy device by the neck or base (See Image 3), holding it with the wider end pointing towards the front (towards the genitals) and the narrower end toward the back. (See Image 3). Place and hold the device in this position over the anus (See Image 2).

4. Use the Hemor~Rite Cryotherapy device for 6 to 8 minutes, or until it reaches body temperature, for a maximum of 10 minutes.

5. Remove the Hemor~Rite Cryotherapy device slowly and smoothly. Wash it with soap and warm water or any external antiseptic. Remove excess moisture with a paper towel and place the dry device in its case.

6. Return the Hemor~Rite Cryotherapy device to the freezer and follow the above procedure for each use.

TREATMENT PERIOD:

Use the Hemor~Rite Cryotherapy device for a minimum of four times daily for the first week of treatment. After the first week, use the Hemor~Rite Cryotherapy device at least twice a day until the symptoms disappear.
Product reusable for a maximum of six months after first application.
Note: Please allow a minimum of two hours between each treatment.

- The Hemor~Rite Cryotherapy device is for personal anal use only and should be kept in its sanitary case when not in use.

HEMOR~RITE Cryotherapy

- Do not introduce the Hemor~Rite Cryotherapy device in to the rectal canal without lubrication.
- The cooling material contained in the Hemor~Rite Cryotherapy device may be toxic.
- Only the neck of the Hemor~Rite Cryotherapy device should be inserted into the rectal canal.
- For advanced hemorrhoidal conditions, grades 3 and 4, the Hemor~Rite Cryotherapy device should be used for external hemorrhoidal treatment only. Once the swelling and the condition of the hemorrhoids have improved, you may then proceed to the internal hemorrhoidal treatment.
  Third degree (3) hemorrhoids prolapse with defecation but recede only by manual reduction. Fourth degree (4) hemorrhoids are permanently prolapsed and cannot be reduced into the anal canal.
- Do not use if you have an elevated reaction to extreme cold or Cryotherapy.
- Keep out of reach of children.
- Hemor~Rite Cryotherapy is a drug free treatment. No prescription needed.
- Hemor~Rite Cryotherapy device should not be taken apart.
- Hemor~Rite Cryotherapy device should not be used in pregnant women or children without prior approval of a physician.
- Hemor~Rite Cryotherapy device is flammable once ignited, may burn rapidly.
- Stop Hemor~Rite Cryotherapy treatment and consult a physician if symptoms continue past seven (7) days or bleeding continues.

Hemor~Rite Cryotherapy is an anatomically designed medical device ergonamicly shaped for application of cold therapy (Cryotherapy) directly to swollen hemorroidal veins of external hemorrhoids and internal hemorrhoids within the rectal canal. The direct application of cold provides prompt relief of itching, pain, and swelling. The device consists of a sealed applicator containing a coolant formula. The Hemor~Rite device is placed into the user's freezer until frozen. After the Hemor~Rite Cryotherapy device is frozen, the user inserts the device to te affected hemorrhoidal area. The probe is maintained in the area for 6-8 minutes, until the probe reaches body temperature, or up to a maximum of 10 minutes. The Hemor~Rite Cryotherapy device is a reusable device.

4. Predicate Device (ANUICE) Technological Characteristics

Anuice is comprised of three pieces of plastic; two of them together and one of them as well by expansion of a pipe inside another.

DESIGN: The pipe of insertion is totally straight, without curves on the end. The base is taller in height than in width and once it is utilized, it should be stored in the appropriate position. The union of both components (tube and body) is done in the zone where the disposition is inserted.

SIZE: The inserted tube is 2 ¾" in height and 2 7/8" in length. The diameter width is (maximum) 15/16".

5. HEMOR~RITE Technological Characteristics

Hemor~Rite is comprised of two pieces of plastic; the crown and the base.

HEMOR~RITE Cryotherapy

DESIGN: The crown of insertion is slanted with curves on the end. The base is taller in height than in width. The union of both components (crown and body) occurs at the base.

SIZE: The crown is 1 51/64" in height and 1 9/32" in length. The diameter width is (maximum) 1 9/32". The base is 9/32" height and 2 7/16" in length. The diameter width is (maximum) 1 9/32".

6. Clinical Performance

Substantial equivalence was based on an assessment of clinical performance data, including:

a. Accelerated Aging and Integrity

b. Investigation of Compression Strength

c. Cytotoxicity

d. ISO Intracutaneous

e. Maximization Sensitization

The results of the testing conclude that Hemor~Rite is substantially equivalent to ANUICE and is safe, as effective, and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 2005

FAMA Holdings International Corp.
c/o Christine M. Humphrey, Esq.
C. Humphrey & Associates, P.A.
801 Brickell Avenue
Suite Nine Hundred
MIAMI FL 33131

Re: K042564
Trade/Device Name: HEMOR~RITE CRYOTHERAPY
Regulation Number: None
Regulatory Class: Unclassified
Product Code: LKX
Dated: September 26, 2005
Received: September 30, 2005

Dear Ms. Humphrey:

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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. 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 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.
In addition, we have determined that your device kit contains a glycerine lubricant which is subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

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, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

HEMOR~RITE
Cryotherapy

INDICATIONS FOR USE

510(k) Number (if known): **K042564**

Device Name: **HEMOR~RITE CRYOTHERAPY**

Indications for Use:

The device use is for the treatment of hemorrhoids by applying it directly to the swollen hemorrhoidal tissues. By applying the device to the tissue, the inflammation is reduced. The base section is used for the treatment of external hemorrhoids and the neck/probe section is used for the treatment of internal hemorrhoids. The lubricant is used to ease the introduction of the probe into the rectum.

Prescription Use (Part 21 CFR 801 Subpart D) _____ AND/OR Over-The-Counter Use ✓ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Jegerson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042564