APIMEDS Inc.

PROJECT NAME (Ingredient Trade Name): Extt-101(Perineometer, Biofeedback Kegel Exerciser) **Active Ingredient Scientific Name: The Product received from the authorities as a medical device and Does not necessary active ingredient.** **Submission Date: Mar. 18, 2010**
Description of Product: In the developed countries, urinary incontinence is considered as a social cancer. The Perineometer (ExTT-101) used to diagnose and correct urinary incontinence and female sexual dysfunction by measuring the contraction pressure of the vaginal floor muscles (pelvic floor muscles) and enabling treatment all at the same time.

1. Supporting Evidence (Efficacy/Functionality):

Provide all supporting literature and research studies, publications, protocols, and analytical assessment.

Please separate data into:

■ Mechanism of Action/s (MOA)

In the developed countries, urinary incontinence is considered as a social cancer. The Perineometer (ExTT-101) used to diagnose and correct urinary incontinence and female sexual dysfunction by measuring the contraction pressure of the vaginal floor muscles (pelvic floor muscles) and enabling treatment all at the same time.

Unlike current diagnosis where women have to go to the hospital and undergo a contraction pressure test performed by a physician, women now can discreetly test themselves for urinary incontinence in the privacy of their home. The Perineometer (ExTT-101) enables women to self-diagnose and treat her symptoms all at once. Just as physicians diagnose these problematic symptoms with pelvic strengthening exercises, this device will allow women to self-diagnose and then perform the necessary treatment.

- Extt-101 World First 3Way-4Channel System.
  - 1way : Self-Examining / Measurement
    - ✓ Measurement of Squeezing Pressure
    - ✓ Measurement of Resting Pressure
    - ✓ Measurement of Squeezing Duration Time
  - 2way : Self-Training / Kegel Exercise
    - ✓ Exerciser Feedback : Probe
    - ✓ Light Sense Feedback : LCD Display
    - ✓ Acoustic Feedback : Sound Output
    - ✓ Sensory Feedback : Vibration Probe
  - 3way : Self-Therapy / Treatment
    - ✓ Vaginal Relaxation Therapy
    - ✓ Incontinence Therapy
    - ✓ Sexual Disorder Therapy
    - ✓ Stress / Music Therapy

■ Chemistry/Characterization data

This product is physical medical device so that does not necessary a chemistry data.

■ *In vitro* bioassay data

This product is physical medical device so that does not necessary a vitro bioassay data

■ *In vivo* testing (Laboratory, Animal, and Human Clinical Studies)

The Extt-101 is the class-Ⅱ medical device which already received permission from the authorities without the vivo testing. However We are doing the vivo testing for an objective validity and public confidence data. In addition, to be recognized from the overseas market and domestic market we do the vivo test in process.

■ Clinically tested

- ✓ Clinical Project Name : Comparison efficacy study of Perinometer (ExTT-101) biofeedback therapy on SUI (Stress Urinary Incontinence)
- ✓ Project manager / institute : Prof. Hong-Tae, Noh / Chung-nam University hospital gynecology

<table>
<tr><td>*Clinical Trial Organization</td><td>Chung-nam University Hospital</td><td>Organizing Agency</td><td colspan="2">APIMEDS Inc.</td></tr>
<tr><td rowspan="2">Clinical test Title</td><td rowspan="2">Comparison efficacy study of Perinometer (ExTT-101) biofeedback therapy on SUI (Stress Urinary Incontinence)</td><td rowspan="2">Clinical test type</td><td>☐ Medical device Clinical Test</td><td>(✔Domestic/☐Oversea)</td></tr>
<tr><td>☐ Others</td><td>(☐Domestic/☐Oversea)</td></tr>
<tr><td>*Clinical Test Frequency</td><td>1 (in progress)</td><td colspan="3"></td></tr>
<tr><td rowspan="2">Total research period (2009)</td><td rowspan="2">First-year</td><td rowspan="2">Necessary Period</td><td colspan="2">Total research period : Aug. 09~ Jul. 10 (12 Month)</td></tr>
<tr><td colspan="2">Research period in present year : Aug. 09~Jul. 10 (12 Month)</td></tr>
<tr><td>* Design of Clinical Trial</td><td colspan="4">▣ Purpose of Clinical Test
- Purpose
1) It evaluates to affect to the improvement of incontinence from the pelvic floor exercise of the incontinent patients by using Perineometer (ExTT-101).
2) The treatment of result from the vaginal maximal pressure and the duration of vaginal contraction by Perineometer(ExTT-101) and analyze the differences between before and after.
- Needs : To provide the Clinic Data about the detailed efficacy for the Using this medical device by the medical professionals and the consuming public.
▣ Contents of the Clinical Test.
1. Target patients and Number of patients
- Disease of Target patients : Stress Urinary Incontinence (SUI)
- Expect number of patients on clinical test in this year : 100 patients
- Number of total patients for the completion of the clinical test : 100 patients
2. composition of test group
- The 100 selections of SUI patients by the urodynamic inspection.
- Case Group (35) : Using Extt-101 normally
- Placebo Group(35) : The group of placebo Using Extt-101 with low degree of air pressure in the probe.
- Control Group (30) : Carrying out the Extracorporeal Magnetic Innervations
3. Testing Methods
- To evaluate the suitability and collect the fundamental information on the first visiting. After complete the evaluation, the patient takes part in the study and classification in random. The every patients measure initial test(urodynamic test, urine test) and conduct the measurement using Extt-101.
- The group of placebo also uses Extt-101, however turning the air pressure of vaginal probe down so that there is no affection of the using Extt-101 (8 Weeks, 3 times a week, 20 minutes each time)
- The case group should use the Extt-101 correctly. (8 Weeks, 3 times a week, 20 minutes each time)
- The control group conducts the ExMI (8 Weeks, 2 times a week, 20 minutes each time)
- All of patients must visit the hospital for the treatment.
- The evaluation of every patient is bellow.
①Initial visit ②2nd week ③4th week ④6th week ⑤8th week
- Measuring by the Extt-101, then conduct the urodynamic inspection on last 8th</td></tr>
</table>

	week. vaginal resistance pressure, volume, maximum holding duration time) - Questionnaires Test 4. Clinical Evaluation Index - Vaginal Pressure : Comparing between the fist visit and 8 weeks later one - Urodynamic Test : Comparing between the fist visit and 8 weeks later one
*Respondent Rate (%)	Postponing the total amount of respondent until Complete the clinical trial, due to the Clinical Trial is in progress.
*Resister in the journal	We are progressing the Clinical trial for the announcement of SCI thesis.
* organization, professor or university for the joint research,	We have been collaborating since the first step of development with MD. Anna Jakubowska in Women's Urological Research Center, USA for the find an overseas market.
* Conclusion of Clinical Test	We are progressing the Clinical trial for the announcement of SCI thesis

2. Intellectual Property / Exclusivity

Provide an IP Portfolio summary to include:

- Provide patent information
  - Provisional/non-provisional/PCT/

(See. Attachment 1)

- Patent Title : An apparatus for examining and curing Urinary Incontinence, and for exercising Biofeedback of women's vaginal muscles
- Patent Registration : No.10-0710908 (2007.04.17)
- International Patent : PCT KR2006-002554 (2006.06.30)
- US Patent : No. 11/795882
- EU Patent : No. 06769123.8
- Japan Patent : NO. 4153027(2008.07.11)
- China Patent : No. 200680009192.6
- India Patent : No. 6035/DELNP/2007

  - How is the patent unique, compared to competition?

Unlike current diagnosis where women have to go to the hospital and undergo a contraction pressure test performed by a physician, women now can discreetly test themselves for urinary incontinence in the privacy of their home. The ExTT enables a woman to self-diagnose and treat her symptoms all at once. Just as Physicians diagnose these problematic symptoms with pelvic strengthening exercises, this device will allow a woman to self-diagnose and then perform the necessary treatment.

  - Number of patents?

Total 7 Patents

- Describe exclusivity options (MLM, all markets, global, etc.)

We have been done the registration of China Patent and Japan Patent by the current patent law. In addition we are planning to get the exclusive right in PCT, US, EU, and India through a patent application.