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510 (k) Summary

NEBL Restore Female Continence Cap

1. Name: NEBL, Inc  
Address: 44 Terrace Drive  
Worcester, MA 01609  
Phone: 508-466-7639  
Contact: Jeffrey Dann, M.D.  
Date prepared: 4/7/97

NOV 14 1997

2. Device Name:

Proprietary Name: Restore (a.k.a. Capsure)  
Common Name: Female Continence Device  
Classification Name: Incontinence Urethral Occlusion  
Device  
Classification Code: 78MNG

3. Predicate Devices: NEBL CapAid Device  
ASI/Urómed Miniguard

4. Device Description

The Restore Female Continence device is a simple, non invasive suction cup device which fits over the urinary meatus. Similar to a suction cup, air is squeezed out of the device's cap while it is positioned over the urinary meatus. When the cap is released, the device self-adheres to the anterior vaginal wall over the meatus via self-suction. If inadequate suction occurs, Aquaphor or an equivalent ointment can be applied to the outside rim of the device to enhance adhesion. The suction or negative pressure created by the device causes coaptation and occlusion of the meatus and, therefore, increased urethral resistance. The amount of negative pressure generated by the device is optimized to counteract increases in intra-abdominal and intravesical pressure during valsalva thereby decreasing or preventing leakage.

5. Intended Use:

The Restore Continence Device is an external continence device designed to effectively occlude the meatus, thereby decreasing or preventing episodes of urinary stress incontinence.

6. Indications for Use:

The Restore Continence Device is an external female continence device indicated for the management of urinary leakage in women suffering from stress urinary incontinence. Although it can help control urinary incontinence, it will not correct the underlying cause of the condition.

## 7. Substantial Equivalence Comparison

The Restore Continence Device is substantially equivalent to the NEBL CapAid Incontinence Device. Both the Restore and the CapAid Device achieve the intended use (to prevent or decrease episodes of incontinence) by occlusion of the urethra. Both devices are worn externally, adhere to the external genitalia and occlude the meatus. Patients remove both devices to void and reapply after micturition is completed. The Restore device also has technological similarities to the Miniguard Device. Both are placed intralabially and occlude the urethral meatus by creating a seal over the urinary opening.

## 8. Non clinical Tests

Restore and its constituent materials were tested for biocompatibility, toxicity, and cytotoxicity, bacteriostasis/fungiastasis, skin sensitivity and 90-day muscle implantation studies. The testing meet the guidelines and requirements for long-term implantation. The results of these tests demonstrated that the materials and the whole device are biocompatible, nontoxic and well tolerated by cutaneous and subcutaneous tissue. In addition, bacteriostatic testing indicated that the materials do not support growth of common urologic pathogens.

Bench testing of the Restore device constructed of Applied Silicone LSR 30/40 LT creates approximately 150 cmH<sub>2</sub>O when applied to a siliconized digital pressure gauge. This negative pressure is optimal in counteracting increased intravesical forces during valsalva, thereby preventing leakage due to stress incontinence.

9. Clinical Tests

The Restore device has been extensively tested for its safety and efficacy in decreasing or preventing incontinence episodes in women. All testing results indicate that the Restore device provides minimal risk yet provides significant benefit for women in controlling urinary leakage.

Effectiveness

Clinical testing was completed on 100 women from 8 Investigational Sites in the U.S. Women used the Restore device during a device usage period of 12 weeks to test the efficacy hypothesis that the Restore Continence Cap will: 1) decrease or prevent incontinence episodes and 2) reduce the impact of incontinence on quality of life. Objective testing included Pad Weight Test (PdWt) and Provocative Stress Test (PST). Subjective testing included a voiding diary documenting the number of incontinence episodes per day (IEPD), an incontinence impact questionnaire and a satisfaction survey. Efficacy parameters were statistically analyzed using paired t analysis, repeated-measures analysis and Wilcoxon signed rank testing. Analysis demonstrates a statistically significant improvement in all objective and subjective efficacy measures. The Table below details the average measurements before device use (Control) and at the Week 12 Device Utilization Visit.

<u>Test</u>	<u>Control</u>	<u>Week 12</u>	<u>%Improvement</u>	<u>P</u>
PdWt	6.67gm	.19gm	97%	.0001
PST	2	0	100%	.0001
IEPD	3.4	.3	91%	.0001
I-QOL	62.3	90.4	45%	.0001

Breakdown by Visits demonstrated that the effect was immediate with continued improvement as patients became more proficient with device placement.

The women in the Study were stratified into categories of mild (0-2gm), moderate (2-8gm) and severe (greater than 8gm) urinary incontinence based on Baseline Pdwt. Analysis of Pdwt results demonstrate a statistically significant improvement in urine loss for each subpopulation of subjects.

The impact of urinary incontinence or quality of life is a measure of the patients perception of the degree to which leakage had a negative effect on various aspects of daily living. A 22 question incontinence impact questionnaire (I-QOL) with a maximum score of 110 evaluated subjects before and during device usage. Subjects demonstrated a significant improvement in their quality of life during device use.

Patient Satisfaction Surveys evaluated specific aspects of Restore's function, comfort and ease of use. Mean Response and Rate of Positive Response analysis demonstrated high scores of ease of placement and removal, convenience and ability to remain in place during activity. Patients were satisfied with overall device performance in restoring continence, improving enjoyment out of life and self confidence. Finally, patients demonstrated a high degree of satisfaction with device comfort.

A six week Post Device Utilization Period assessed subjects degree of urine loss after device discontinuation. Pdwt, PST and IEPD testing demonstrated statistically significant improvement in urine loss during this period compared to the Baseline control. This response, however, deserves further investigation before any long term therapeutic claims can be made.

### Safety

To provide clinical safety assurance of the Restore Continence Cap, objective assessment of Safety included 1) urine cultures 2) irritation questionnaire and 3) periodic physical examinations.

Frequent urine cultures revealed a 1.5% prevalence and 3% incidence of positive urine cultures during device usage. Based on literature review of the age-specific prevalence of bacteriuria in incontinent females, this low prevalence rate is significantly below historic figures of 10-38%.

Satisfaction Survey Question 8 quantitates vaginal irritation. The Mean Response and Rate of Positive Response were relatively high throughout The Study signifying that the Restore device was well tolerated in the vast majority of patients.

Adverse events on physical examination were few, minimal, self limited and usually related to incorrect device placement. No therapeutic intervention was required in any patients and no complications or sequelae occurred.

Analysis of patients withdrawing from The Study demonstrated that the most common reason cited was inability to keep scheduled visits. Only 5% withdrew because of vaginal irritation. Furthermore, PdWt and PST demonstrated a statistically significant improvement in urine loss in this subgroup during device use which was equivalent to subjects completing The Study.

#### 10. Conclusions

The safety of the Restore device was demonstrated by extensive biocompatibility testing and non clinical and clinical testing. Technological characteristics do not raise new types of safety and effectiveness questions relative to predicate devices. The Clinical Study demonstrated that the Restore device did not effect the incidence or prevalence of significant bacteriuria. The device was well tolerated by the vast majority of patients. The efficacy of the Restore device was demonstrated by both objective and subjective measures. The clinical data showed that statistically significant improvement was obtained by subjects using Restore. In summary, these data provide reasonable assurance that the Restore Female Continence Cap is a safe and effective alternative for Women requiring stress incontinence management and is statistically equivalent to the predicate device.



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Document Control Room W-O66-0609  
Silver Spring, MD 20993-0002

APR 26 2010

Jeffrey A. Dann, M.D.  
President  
NEBL, Inc.  
44 Terrace Drive  
Worcester, MA 01609

Re: K971359  
Trade/Device Name: RESTORE (a.k.a. Capsure)  
Regulation Number: 21 CFR §876.5160  
Regulation Name: Urological clamp for males  
Regulatory Class: I  
Product Code: MNG  
Dated: August 25, 1997  
Received: August 28, 1997

Dear Dr. Dann:

This letter corrects our substantially equivalent letter of the original SE letter November 14, 1997.

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 (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 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.

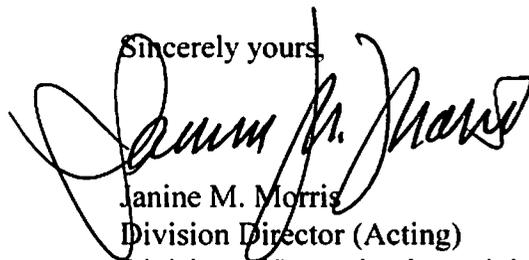
Page 2 Dr. Jeffery Dann  
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations, 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 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,



Janine M. Morris  
Division Director (Acting)  
Division of Reproductive, Abdominal, and  
Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

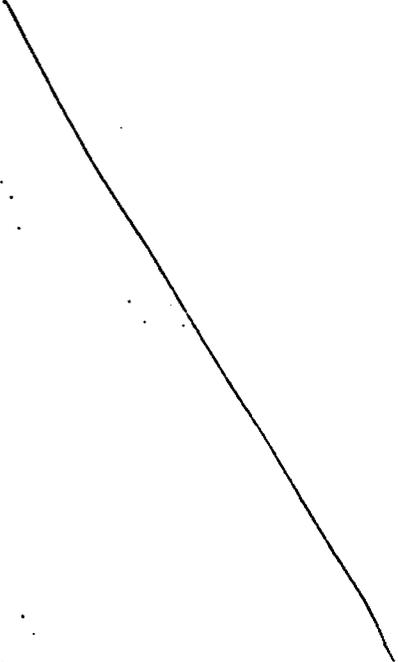
Enclosure

510(k) Number (if known): K# 971359

Device Name: NEBL, Inc. Restore Device

Indications For Use:

The Restore Continence Device is an external female continence device indicated for the management of urinary leakage in women suffering from stress urinary incontinence. Although it can help control urinary incontinence, it will not correct the underlying cause of the condition.



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Concurrence of CDRH, Office of Device Evaluation (ODE)

Dale R. Rattner  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K 971359

Prescription Use   
21 CFR 801.109

OR

Over-The-Counter Use

(Optional Format 1-2-96)

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