Seager Electroejaculator
Summary of Safety and Effectiveness

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7.0 Summary of Safety and Effectiveness

Indications for Use

The Seager Model Electroejaculator (EE) is intended to induce seminal emission in patients for whom prior or present illness precludes their ability to spontaneously ejaculate. The EE device is indicated for use in neurologically impaired males who are 18 yrs. and anejaculatory due to the following conditions:

Spinal Cord Injury (paralysis)

Retroperitoneal Lymph Node Dissection (RPLND) [surgical therapy post testicular cancer]

Idiopathic (neuropsychosis/psychogenic)

Diabetes

Spina Bifida

Pelvic Surgery Complications

Multiple Sclerosis (MS)

Neurological Impairments

The EE device is contraindicated in the following individuals:

Chron's Disease

Ulcerative Colitis

Rectal cancer or other significant rectal pathology

Patients with pacemakers or other artificial heart device

Alternative Treatments

Other available methods of inducing ejaculation in neurologically impaired individuals include vibration, (success limited to those with high SCI lesions) or invasive procedures such as vas aspiration, epididymal aspiration and testicular aspiration or biopsy.

Historical Development of Electroejaculation

The first study of electroejaculation in neurologically impaired males (Horne et al, 1948[1]) reported successful ejaculation in 11 of 18 (61%) participants. The authors used low level electrical current (45-60

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milliamperes) to stimulate the prostate and seminal vesicles. Between 1948 and 1962, three additional reports described efforts to electrically stimulate the prostate in both intact and spinal cord injured males (Bors, Engle, Rosenquist & Holliger, 1950[2]; Potts, 1957[3]; Rowan, Howley & Nova, 1962[4]). None of these studies reported successful production of ejaculation.

Subsequent studies in both animals (Francois, Maury, Vacant, Clukier & David, 1975[5]) and humans (David, Ohry & Rosen, 1977-78[6]; Francois, Maury, Javonnet, David & Vacant, 1978[7]) provided further experience with electroejaculation that led to a series of landmark articles by Brindley (1980-1984[8-10]) describing his experience with EE in over 100 spinal cord injured men. His work represented the first in depth examination of 1) electrode positioning to achieve more precise stimulation of anatomic structures;
2) previous animal experience in EE with non human primates;
3) various aspects of technique, equipment and safety issues involved in EE; 4) the correlation of anatomic and physiological factors with successful stimulations; and 5) the first attempt to correlate level of injury and successful ejaculation (none was noted).

A study by Martin et al (1983) examined the safety parameters of repeated electrical stimulation to the rectal mucosa. The authors examined the effect of low level electrostimulation (ES) in both intact (N=8) and SCI males (N=12). The pain resulting from ES precluded erection or ejaculation in intact men. However, minimal discomfort was experienced by spinal cord injured subjects. Rectal scopic exams post stimulation showed mild erythema due to the heating of the rectal mucosa. The number of patients demonstrating this finding, the length of stimulation, stimulation parameters, or any attempt to directly measure local mucosal temperature was not mentioned.

The first attempt to evaluate the effect of chronic electrostimulation (ES) in an SCI animal model was reported by Seager et al. in 1984[11]. Rectal stimulation was applied in a group of 12 monkeys with transected spinal cords (and a control with intact spine) on a monthly basis for over two years. Ejaculation was achieved in all animals. Autopsy studies revealed no abnormalities associated with chronic ES and tissue samples from the rectum, seminal vesicles, prostate, testes and epididymis were normal.

Based on this experience in SCI monkeys, as well as 20 years of prior research with over 100 species of animals (Seager, Wildt & Platz, 1980[12]; Seager, 1983[13]) the electroejaculation technique was refined to the procedure used in the study reported herein.

Device Description and Principle of Operation

The Seager EE device consists of a power unit and rectal probe which is designed to provide low level (5-10 volts) electrical stimulation. The rectal probes vary in diameter from 1 inch to 1 5/16 inches. Prior to

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the procedure, a rectal exam is performed to determine the correct probe size and assure that the rectal mucosa are not compromised. For spinal cord injured patients with lesions at T-6 or above, or patients at risk of dysreflexia (elevated blood pressure), this may be controlled with appropriate medication (e.g. Procardia; nitrogylcerine). For non spinal cord injured patients whose lesion may be incomplete, short general anesthesia (GA) may be administered.

The rectal probe is inserted into the rectum and a series of low level electrical stimulations are delivered to the prostate gland and seminal vesicles. Once the patient begins to ejaculate (usually after 5 to 10 stimulations), additional stimulations (10 to 12) are applied to obtain the entire ejaculate volume. During the procedure, patient comfort and blood pressure are monitored. If blood pressure increases above 180 systolic and/or 120 diastolic, the procedure is halted until pressures return to normal and the patient wishes to continue. After discontinuation of rectal stimulation, blood pressure is monitored until it returns to normal physiological levels. Following the procedure, the rectal mucosa is re-examined to assess any changes from pre-stimulation.

Support for Substantial Equivalents of Seager Electroejaculation Equipment as compared to similar equipment developed by Mr. A. Stiebel.

Mr. Stiebel's electroejaculation equipment was patented October 1, 1958, U.S. Patent Number 3403684. The device was an electric probe placed in the rectum for bringing about ejaculation in spinal cord injured and other neurologically impaired men. Seager was also granted a U.S. Patent Number 07 701815, filed May 20, 1991, that used a similar technology of placing a probe in the rectum and then by electrical impulse bringing about ejaculation in the same patient population.

The approximate weight and the shape of the probes are the same. The diameters: A. Stiebel's is 1 inch; Seager's is 1 1/4 inch. The intended use and the placement of the probes is the same. Sterilization methods are also the same.

Mr. Stiebel built his equipment with the help of persons who were involved with spinal cord injury as did Dr. Seager. He has certified that he made significant attempts to market this device both inter and intra-state and also in foreign countries.

The intention of this 510k application is to demonstrate substantial equivalents to this very similar device.

Material Biocompatibility Studies

The rectal probe, which comes into short-term (3-5 minutes) contact with the rectal mucosa, is manufactured from medical grade (306) stainless steel electrodes embedded in a polyvinylchloride (grade 6 PVC) substrate. Material biocompatibility was evaluated by cytotoxicity (USP elution) and USP intracutaneous toxicity (extracts).

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Testing results indicated that the rectal probe materials were non-cytotoxic and showed no evidence of significant irritation or toxicity when injected intracutaneously into rabbits. Based on the results of these studies, the compatibility of probe materials for short-term rectal mucosal contact were supported.

Results of Clinical Studies

A multi-center clinical investigation to evaluate the safety and effectiveness of the EE device was conducted at 13 sites in the US. A total of 403 subjects participated in a single arm non randomized study to determine if ejaculation could be induced in patients who previously were not able to produce ejaculate normally. The study group averaged 32.6 years of age (range 19 to 60). Patients average age at injury was 23 years (range 0 to 54). Of the 403 patients, 346 (85.9%) were spinal cord injured and 57 (14.1%) were non spinal cord injured.

The effectiveness of the EE device for its intended use was assessed by the production of ejaculate in an otherwise anejaculatory male. In order to confirm the safety of the device, successful ejaculation would be accomplished with minimal risk of dysreflexia (elevated blood pressure) and other untoward events including rectal mucosal burning or perforation.

The safety of the EE device was assessed by examining changes in blood pressure compared to normal physiological range during the procedure and any post-procedure changes in rectal mucosa from pre-stimulation baseline. Systolic/diastolic pressures recorded before, during and at the end of the EE procedure were compared to normal physiological at rest (120/80), normal physiological during exercise (160/100) and normal physiological at rest (120/80) respectively. Other than slightly elevated systolic blood pressures after termination of the EE procedure (3 - 7 mm Hg, $p < 0.01$), average blood pressures during the EE procedure remained well within normal physiological range. The slightly elevated blood pressures observed at the end of the EE procedure resulted in no adverse events for any patient, and were considered clinically insignificant.

Rectal examination after completion of the EE procedure revealed no clinically significant changes from pre-stimulation baseline. No medical complications as a result of the EE procedure were reported for any patient in the study.

The effectiveness of the EE device in inducing ejaculation was confirmed in the clinical study. Of 346 spinal cord injured participants, successful ejaculation was achieved in 340 (98%). Fifty one (89%) of 57 non spinal cord injured patients were able to achieve ejaculation. For spinal cord injured patients, viable sperm were detected in 256 (75%) of the 340 ejaculate samples obtained. For non spinal cord injured patients, sperm were detected in 45 of 57 ejaculate

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specimens (79%).

Conclusions

The results of the clinical study support the safety and effectiveness of the EE device in inducing ejaculation in spinal cord injured and non spinal-cord injured males who do not spontaneously ejaculate by normal means. No adverse events were reported for any individual treated with EE, and blood pressure remained within normal physiological range. Ejaculation was successfully achieved by 96% of spinal cord injured males and 89% of non spinal cord injured males, respectively.

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SEP 18 1997

Re: K962379
Seager Electroejaculator
Dated: July 29, 1997
Received: July 31, 1997
Regulatory class: unclassified
Product code: 78 LNL

Dear Dr. Seager:

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 Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4613. 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,

William Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K962379

Device Name: Seager Electroejaculator

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Pelvic Surgery Complications

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Neurological Impairments

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter R Sathing

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K962379

Prescription Use X OR Over-The-Counter Use