K961817

510(k) SUMMARY

JUL 23 1997

1. COMPANY INFORMATION

Name (Manufacturer)	:	Hayashi Denki Co., Ltd.
Name (U.S. Agent)	:	Koven Technology, Inc.
Address (Manufacturer)	:	7-11 Arima, 2-Chome Miyamae-ku Kawasaki 216, Japan
Address (U.S. Agent)	:	300 Brookes Drive, Suite 105 St. Louis, MO 83042
Telephone (Manufacturer)	:	011-81-44-877-4361
Telephone (U.S. Agent)	:	(314) 731-0008
Contact Person	:	Mr. Paul G. Koven, President Koven Technology, Inc. 300 Brookes Drive, Suite 105 St. Louis, MO 83042 (314) 731-0008
Date Prepared	:	May 8,1996 Revised October 10, 1996 Revised June 11, 1997

2. DEVICE NOMENCLATURE.

Trade Name	:	B SMART™ (Buchbinder Sensory Motor Activated Response Timer)
Common Name	:	Sensory Response Timer
Classification Name	:	Evoked Response Mechanical Stimulator [84 GZP, 882.1880]

3. PREDICATE DEVICE.

Nicolet Biomedical Instruments Corp.	:	Expert Sleep/Wake Analysis System
510(k) Number	:	K873535
SE Decision	:	October 26, 1987

4. DEVICE DESCRIPTION.

The B SMART Sensory Response Timer system consists of two components connected by an electrical cable. These components are a Control Unit and a Finger Attachment. The complete system is shown in Figure 1.

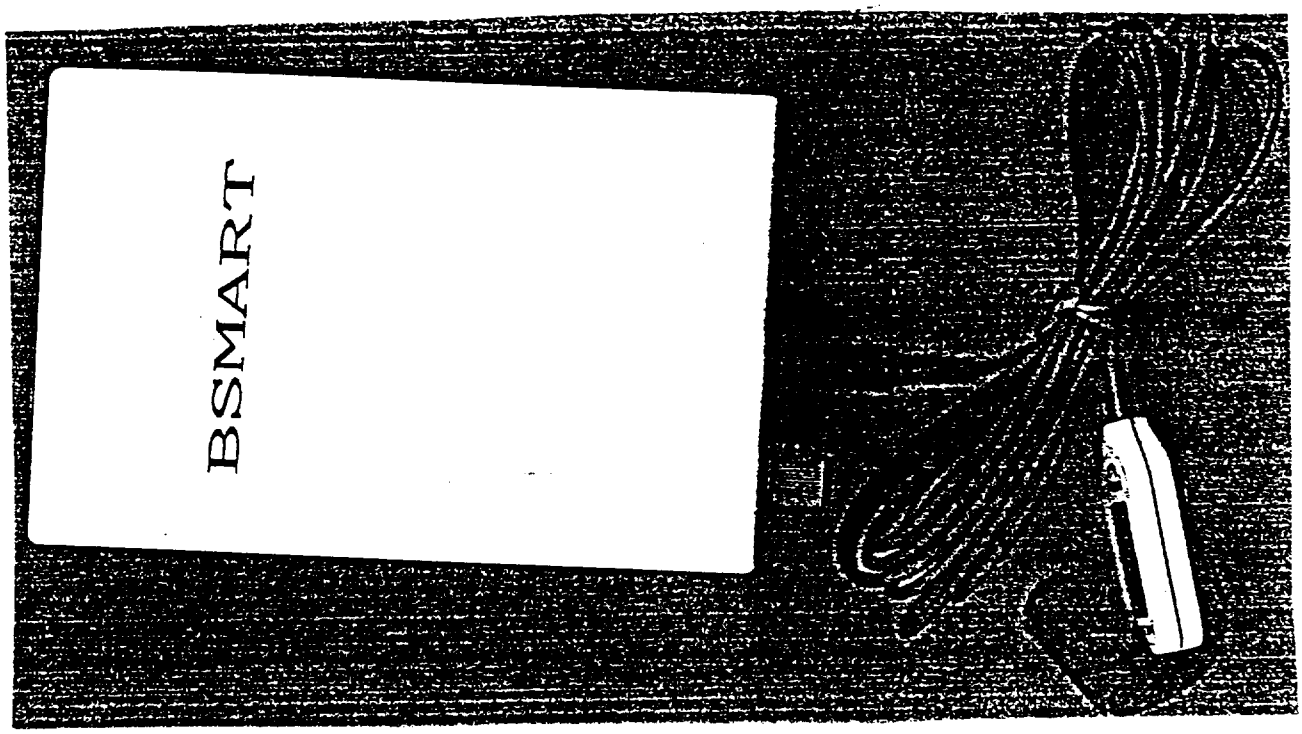


Figure 1. B SMART System (Control Unit and Finger Attachment)

The Control Unit contains a power supply, a cycle timer, an audio tone generator and speaker, and necessary controls, indicators, and connectors. There are three controls: the power on/off switch, the stimulus cycle selector switch which is used to set the interval between successive activations of the stimulator, and an audio tone volume control. The indicators are power-on and battery status (an LED indicator). The connector is a 3.5mm mini-tip receptacle for the interconnect cable. A block diagram of the Control Unit is shown in Figure 2 below:

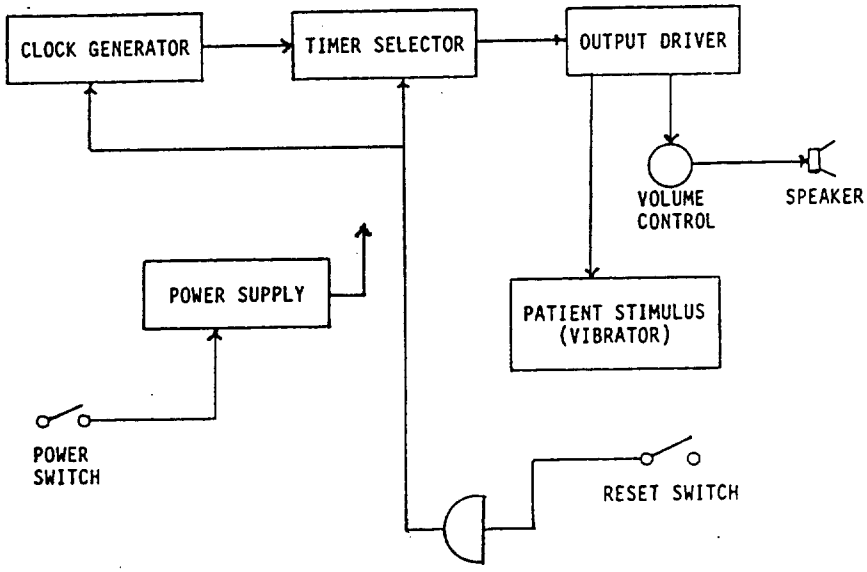


Figure 2. Block Diagram of Control Unit

The Finger Attachment contains a vibratory tactile stimulus mechanism and an impedance-pad-type cycle reset button housed in a small case which is attached to the patient's finger using a Velcro band. When the patient feels the vibratory stimulus (or hears the speaker tone), he or she presses the cycle reset button to terminate the stimuli. Cessation of the audio tone informs the attending physician or nurse that the patient is awake and able to respond. If the audio tone does not cease, the anesthesiologist is alerted that intervention may be needed due to impairment of neuromuscular responsiveness.

For special situations, additional Finger Attachments (up to a total of four) may be connected to a single Control Unit for multiple-site monitoring.

The Stimulus Cycle Selector Switch is a manual slide switch that controls the interval between automatic activations of the patient stimulus test cycle. Any of three intervals may be selected by the operator. The available interval settings are 30, 60, and 120 seconds.

The system is powered by two AA-size 1.5-volt alkaline batteries. Total voltage is 3 volts DC. Upon power turn-on, an LED indicator on the Control Unit flashes on and off for 10 seconds to indicate that battery charge status is adequate for proper operation. If the light fails to come on or no audio tone is heard, the exhausted batteries should be replaced with two AA-size alkaline batteries.

5. INTENDED USES.

The B SMART Sensory Response Timer is indicated for use in evaluating neurological status during surgery under regional anesthesia by monitoring the capability of the patient to detect and to respond to a timed series of mechanical and auditory stimuli.

6. COMPARISON WITH PREDICATE DEVICE.

The subject device, the B SMART system is a patient-activated stimulus/response system intended for use in monitoring neurological status during carotid endarterectomy and related cerebrovascular surgical procedures performed using local or regional anesthesia. The literature states that adequate monitoring is vital during carotid endarterectomy whether performed under general or regional anesthesia to insure that adequate cerebral perfusion is maintained. In addition to ECG and blood pressure monitoring, many different methods of neurological monitoring are in use to detect evidence of cerebral ischemia early enough so that appropriate counter-measures can be instituted.

The choice of monitoring methods is partly determined by the type of anesthesia selected. Many of the institutions where local or regional anesthesia is used during carotid surgery employ very simple monitoring techniques. For example, the anesthesiologist will ask the patient to respond to a handgrip or verbal questions at frequent intervals. Some hospitals use squeeze toys, and others have used fluid-filled plastic bags connected to a pressure transducer.

Although the exchange of hand grips between patient and anesthesiologist, squeeze toys, and fluid-filled bags all have the same intended use as the B Smart system, they are not cleared medical products. It is therefore necessary to compare the B SMART system with more sophisticated equipment capable of being used for the same purpose.

Electroencephalography (EEG) is probably the most widely used form of physiologic monitoring during cerebrovascular surgery. It's use is virtually standard in those patients operated on under general anesthesia. Many surgeons who prefer local or regional anesthesia employ EEG monitoring also. Although conventional EEG is often used, many hospitals employ EEG instrumentation equipped with a computer processing accessory as an aid in interpreting results, which can be difficult if personnel with specific EEG training are not available to assist the anesthesiologist.

The predicate device, the Nicolet Expert Sleep/Wake Analysis System, is a computer processing accessory for use in analyzing EEG and other physiologic signals for the evaluation of waking and sleeping states. Although the program is optimized for use in sleep disorder laboratories, the EEG analysis programming incorporated in the Nicolet system is very similar to the several versions of "processed EEG" widely used in carotid endarterectomy monitoring. When used in the awake patient during surgery under local or regional anesthesia, processed EEG systems monitor the neurological status of the patient and detect lapses into unconsciousness signifying the onset of cerebral ischemia. Therefore, an an approved computerized EEG processing accessory, the Nicolet Expert Sleep/Wake Analysis System, was selected as the predicate device for the B SMART system because it is capable of performing the same function in the same type of patient in the same surgical environment as the subject device.

7. PERFORMANCE DATA.

Buchbinder and Melick studied the performance of a prototype version of the B SMART system over a period of three years in 47 patients in whom carotid endarterectomy was performed under regional anesthesia. Results were reported in a scientific exhibit presented at the 81st Clinical Congress of the American College of Surgeons, New Orleans, LA, October 22-27, 1995.

The B SMART system was employed successfully in 45 of the 47 patients (95.7%). Two patients (4.3%) could not be monitored satisfactorily due to motor impairment caused by partial paralysis from prior cerebral vascular accidents. Monitoring demonstrated proper sensory and motor function during endarterectomy in 44 patients (93.6%). Neurological dysfunction was detected in three patients (6.4%) and was treated successfully by immediate insertion of a temporary shunt.

The B SMART system permits quick and convenient verification of proper operation. Before placement on the patient, the operator can mount the Finger Attachment on his or her own finger and check that the mechanical stimulus is activated and that the cycle reset button turns off the audio tone and that the next stimulus/response cycle occurs at the selected time. A watch may be used to verify performance of the cycle selector switch on the Control Unit.

Electromagnetic compatibility testing was conducted by an independent laboratory. Test results demonstrated that the auditory and vibratory signals produced by the B SMART system conform with specifications for radiated emissions and thus will not cause electromagnetic interference (EMI) with other equipment used in the same environment. The B SMART system was also found to meet EMI immunity standards is that operating integrity is maintained in the presence of electromagnetic signals generated by other emission sources.

8. CONCLUSION.

The intended use of the B SMART Sensory Response Timer is identical to one of the potential diagnostic uses--monitoring consciousness during carotid endarterectomy under regional anesthesia--for which the predicate device may be employed. The subject device raises no new questions concerning safety or effectiveness. All pertinent product data and all required certifications have been filed with the Food and Drug Administration. Koven Technology, Inc. concludes that the subject device is substantially equivalent to devices of the same classification previously legally introduced into interstate commerce in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Paul G. Koven
President and
Official Correspondent
Koven Technology, Inc.
300 Brookes Drive, Suite 105
St. Louis, Missouri 63042

JUL 23 1997

Re: K961817
Trade Name: B SMART Buchbinder Sensory Motor Activated Response Timer
Regulatory Class: Unclassified
Product Code: 84LEL
Dated: June 18, 1997
Received: June 19, 1997

Dear Mr. Koven:

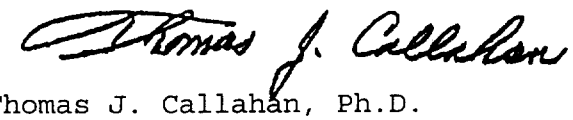
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4648. 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

510(k) Number (if known): K961817

Device Name: B SMART Buchbinder Sensory Motor Activated Response Timer

Indications For Use:

The B SMART Sensory Response Timer is indicated for use in evaluating neurological status during surgery under regional anesthesia by monitoring the capability of the patient to detect and to respond to a timed series of mechanical and auditory stimuli.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K961817

Prescription Use X
(Per 21 CFR 801.109)

[redacted]

(Optional Format 1-2-96)