AUG 27 1999

K983798

Summary of Safety and Effectiveness Information Section 510(k) Premarket Notification **Regulatory Authority:** Safe Medical Devices Act of 1990, 21 CFR 807.92	***SEDATELEC Brand*** **Acupuncture Needles** **SEDATELEC**

1. **Device Name(s):** ASP – Acupuncture Needles
   Common Name: Acupuncture Needles
   Classification Name: Needle, Acupuncture

2. **Establishment Name & Registration Number:**
   Name: SEDATELEC
   Number: 8020802

3. **Classification:** 21 CFR, § 880.5580
   Device Class: Class II
   Classification Panel: General Hospital
   Product Code: MQX

4. **Company Contact:**
   Miss Tonia Courant
   SEDATELEC
   Tel : (+33) 4 72 66 33 22
   Fax : (+33) 4 78 50 89 03

   Submission Correspondent:
   Mr. David W. Schlerf
   Buckman Company, Inc.
   200 Gregory Lane, Suite C-100
   Pleasant Hill, CA 94523-3389
   925.356.2640 - 925.356.2654 - fax

5. **Special Controls:**
   Special controls for this device type do not exist.

6. **Substantially Equivalent Device(s):**
   Seirin – S & Seirin – Pionex acupuncture needles.

7. **Device Description:**
   ASP Type needles consists of a short "tack-like" solid stainless steel needle contained in a plastic injector to introduce the needle in the epidermis, to facilitate the delivery of acupuncture treatment. ASP needles are sterile devices for single use only. The "ASP Gold needle" is an "ASP needle" which has been gold plated (an intermediate layer of copper is added between stainless steel and gold). The ASP needles are offered in a single size.

   Intended Use: To pierce the skin in the practice of acupuncture by qualified practitioners as determined by the states.

   Manufacturing Facility: ASP acupuncture needles are manufactured by SEDATELEC a registered, ISO compliant medical device manufacturing facility located in France.

8. Sterilization/Re-sterilization:

The ASP needle are cleaned/disinfected and manufactured in a clean room meeting FED STD 209 E requirements) in accordance with the US GMP requirements (QSR). The devices are supplied sterile and are single use only. No attempt should be made to resterilize the product.

Sterilization method: ASP needles are sterilized by Gamma radiation at a validated dose level of 25kGy (kiloGray). The sterilization process is applied on finished devices following final packaging. The sterilization process is applied in accordance with EN552 and ISO 11137 standards by a qualified sterilizer. All contract sterilizers are registered by the FDA with a Drug Master File type I. Visual indicators and dosimeters are used to verify product sterility. The radiation dose has been validated to get the sterility assurance level of 10^{-6} in accordance with the ISO 11737-1 standard.

9. Equivalency Comparison Table:

Equivalency Comparison Feature	SEDATELEC ASP & ASP Gold acupuncture needles	SEIRIN – S SEIRIN – PIONEX acupuncture needles
Device Type:	Tack	Tack
510(k) number		K970254
Intended use:	Intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states	
Invasive Length (mm)	2.1mm	From 15 to 50mm From 1.5 to 1.8 mm
Gauge (diameter in mm)	0 to 0.7 mm	From 0.22 to 0.26mm From 0.20 to 0.35mm
Needle Tip Shape	Taper	Taper
Needle shape	Harpoon shape	Stylet Thumbtack shape
Biocompatibility	ASTM 430F surgical stainless steel (Standard specifications for stainless steel billet, bar, and wire for surgical instruments F899-84)	Same
Materials	needle: surgical stainless steel (+ a copper layer and a gold layer for ASP Gold)	needle : surgical stainless steel handle : plastic
Labeling	IDENTIFICATION Manufacturer name and address Product name Acupuncture needles Quantity Lot Number STATEMENTS "STERILE" "Use before" "Sterilized by gamma radiation" "For single use" "Do not reuse" "Rx" statement "Do not store at extreme temperatures and humidity" "Do not use if external package has been damaged or blisters previously opened" "Made in France"	IDENTIFICATION Manufacturer name and address Product name Acupuncture needles Gauge, length Quantity Lot Number STATEMENTS "STERILE" "EXPIRY" "Sterilized with Ethylene oxide gas" "For single use only" "Rx" statement "Do not store at extreme temperatures and humidity" "Do not use if package is previously opened or damaged "Made in Japan"

Based on the design, function, intended use and materials of the DN Needles, substantial equivalence is evident. The referenced CARBO brand needles are functionally identical. The anticipated safety and effectiveness of both devices is or may be expected to be the same.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 1999

SEDATELEC
C/O Mr. David W. Schlerf
Buckman Company, Incorporated
200 Gregory Lane, Suite C-100
Pleasant Hill, Caliornia 94523-3389

Re: K983798
Trade Name: ASP Acupuncture Needles
Regulatory Class: II
Product Code: MQX
Dated: July 8, 1999
Received: July 12, 1999

Dear Mr. Schlerf

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K 983798

Device Name(s):

ASP - Acupuncture Needles

Indications for Use:

To pierce the skin in the practice of acupuncture by qualified practitioners as determined by the states.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rebecca Cascante

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983798

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional format 1-2-96)