I certify that, in my capacity as president of Healex Products, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Milton Hodosh, D.M.D.

Milton Hodosh, D.M.D.
Date
Premarket Notification 510 (k) number

K961457

JUL 18 1996

Section 2- Summary & Certification

This product, The Subliminator, is substantially equivalent in terms of safety and effectiveness to the marketed manual injection devices of Astra, Schein, Monoject, Cook-Waite, Septodont, and others. These products have been marketed prior to May 28, 1976, and are used to inject local anesthetics into tissues to produce infiltration and block anesthesia . They can use Lidocaine, Novocaine (Procaine), Polocaine, Ravocaine, Citanest, and Isocaine in predosed glass ampules which are inserted into the manual injection devices prior to administering the local anesthetic into tissues. Our injection device is called the "Subliminator", it also is used for the injection of these local anesthetics packaged exactly the same way ie. in sterile predosed glass ampules which are inserted also into the Subliminator for injection into tissues. In this regard manual injectors and the Subliminator are both substantially equivalent as they are both used for the same purpose and in fact, utilize the same local anesthetics packaged exactly the same way. both are driven by a plunger through a needle into the tissues.

The needles used with the Astra, Schein, Monoject, Cook-Waite, Septodont manual injectors are pre-sterilized (ethylene oxide) by the manufacturer and are disposable. Reusable needles can be autoclaved and used with these manual syringes also, they are attached onto the manual injection devices and the Subliminator in the same manner. Disposable needles are discarded in Sharp's containers as required by OSHA and the reusable needles are placed in sterile bags and autoclaved for future use. Our Subliminator (motorized, controlled delivery device) utilizes the identical needles in an identical way ie, they are either disposable or reusable, attached onto the Subliminator, discarded after use in Sharp's containers when they are removed, and sterilized exactly the same as described above. In this regard also, the manual syringes cited and our Subliminator are substantially equivalent.

Manual syringes and the Subliminator both employ a piston which engages the rubber plunger of the fluid filled ampule so as to push the plunger forward driving the fluid through the lumen of the needle. In this regard also the manual syringe and the Subliminator are equivalent.

The manual devices and our Subliminator both have the capability to aspirate to determine if the needle has been inadvertently inserted into a blood vessel, an undesired happening. This is a very important feature of both devices, as it is important to have the capability to aspirate in order to prevent the clinician from injecting anesthetic into blood vessels and shocking the patient's vascular systems . Having this capability prevents untoward Syncope and/or Vagal/Vagal reactions The clinician will know not to proceed with the injection, and to withdraw the needle out of the blood vessel, change the direction (angle) of the needle penetration, redirect the needle and aspirate to confirm that their needle is not in a blood vessel. If not in a blood vessel the injection can be continued. Both devices possess this safety (feature). With the manual syringe the clinician would draw back on the plunger manually and observe if blood enters the ampule.
With the Subliminator all that is necessary is to remove the finger from lever A (see schematic 1 w/ legend) and if the clinician is in the blood vessel a stream of blood will enter the glass ampule.

Both mechanisms are effective and in this regard our Subliminator is substantially equivalent to the manual devices cited and marketed prior to May 28, 1976.

Section 3 Proposed Labeling

The Subliminator will be packaged in a box and sold to dentists and physicians for the surgeless delivery of local anesthetics (and fluids) into tissues. It will be featured as being ergonomically designed for controlled (motor driven), slow uniform, surgeless delivery of these fluids. This results in diminished injection pain when compared to manual injections using hand syringes.

Instruction for use

Topical anesthetic is applied to the tissue site where the injection of local anesthetics (fluids) are to be given. A sterile needle (disposable or reusable) of the proper gauge is attached to the Subliminator, and the desired local anesthetic is inserted as well. The Subliminator is held in a pen grasp and the forward lever (A) is activated by depressing it with the forefinger. The first green light will go on and the local anesthetic will flow at the slowest rate. The tip of the needle with local anesthetic flowing is inserted into the tissues to only a depth of 1-3 millimeters. It is kept at this depth for several seconds and then slowly moved in the desired direction and depth. Pain from needle advancement is diminished since the flow of anesthetic precedes needle penetration.

When the clinician deems it important he or she merely has to take their finger off lever A and aspiration will take place automatically. There are two additional forward speeds and they can be employed to speed up the injection once anesthesia has begun and the possibility of pain in the tissues is eliminated. Note that there are two additional green lights indicating the forward speed status.