

K952683

APR - 1 1997

EXHIBIT #11  
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510(K) SUMMARY APEX MEDICAL CORP.,  
PORTABLE INTERFERENTIAL STIMULATION DEVICE  
IF-4000

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K952683

1. Submitter's Identification:

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Date Summary Prepared: December 30, 1996

2. Name of the Device:

IF-4000

3. Predicate Device Information:

IF-4150

4. Device Description:

The IF-4000 generates small pulses of electrical current. Delivered along lead cables to electrodes placed on your skin, these pulses pass through the skin and activate underlying nerves. The relief from chronic and acute pain that the IF-4000 can provide results from this electrical stimulation.

5. Intended Use:

This device is an interferential stimulator with TENS indications used for symptomatic relief and management of chronic pain and/or as an adjunctive treatment for the management of post-surgical and post-traumatic acute pain.

**6. Comparison to Predicate Devices:**

IF-4150 is with the timer and protection with high voltage. IF-4000 is without the timer and stable voltage. Please refer to chart below:

**COMPARISON BETWEEN IF-4000 AND INF 4150/A**

<b>BRAND NAME</b>	<b>IF-4000</b>	<b>INF 4150/A</b>
<b>MAKER</b>	APEX MEDICAL CORP.	BIOMEDICAL LIFE SYSTEMS, INC.
<b>510(K) NUMBER</b>	K952683	K921441
<b>CARRIER FREQUENCY</b>	4000 Hz, fixed	4000 Hz, fixed
<b>DIFFERENCE FREQUENCY</b>	1-150 beats per second, adjustable	1-150 beats per second, adjustable
<b>OUTPUT CURRENT</b>	0-29 milliamps, adjustable	0-50 milliamps, adjustable
<b>OUTPUT VOLTAGE</b>	0-14.5 volts (29 volts peak to peak)	0-25 volts (50 volts peak to peak)
<b>WAVEFORM</b>	symmetric bi-phasic square	symmetric bi-phasic square
<b>PULSE WIDTH</b>	125 microseconds for each phase	125 microseconds for each phase
<b>MAX. CHARGE PER CYCLE</b>	7.25 microcoulombs	12.5 microcoulombs
<b>POWER SOURCE</b>	9V alkaline battery or adapter	Four 1.5V alkaline batteries or optional wall adapter
<b>SIZE</b>	2.4" x 3.5" x 1.1"	2.75" x 4.5" x 1.5"
<b>FREQUENCY SHIFT OPTION</b>	Continuous, 1/1 abrupt, 8/8 abrupt, 10/10 ramped	Continuous, 1/1 abrupt, 8/8 abrupt, 10/10 ramped

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

The following non-clinical tests were performed and met required standards specifications:

- a) UL-544
- b) AAMI/ANSI NS-4 Specifications for TENS Devices
- c) EMC Testing
- d) Allowable variations in supply voltage
- e) Patient Applied Risk Current

8. **Discussion of Clinical Tests Performed:**

Non applicable.

9. **Conclusions:**

The IF-4000 is as safe as effective as the predicate - which is the INF-4150.