

K942434

DEC 14 = 1994

V. SUMMARY OF SAFETY AND EFFECTIVENESS

Bionaire Inc., is submitting a 510(k) for its family of recirculating air cleaners, (Clear Air Air Purifiers and Ionizer) primarily intended for use in home and office applications to remove airborne particulate matter in the sub-micron size range. These products utilize electret/carbon filtration systems in conjunction with ion generators.

Bionaire's products are claimed to be substantially equivalent to: (1) Enviracaire's EV-10, EV-15 and EV-25 products, which have the same intended use, but which utilize a HEPA filter in conjunction with a carbon prefilter; and (2) Hunter Fan's 30100 and 30300 products, which have the same intended use and utilize the same electret/carbon filtration system as Bionaire's products.

To support substantial equivalence to predicate products, Bionaire's products have been tested in accordance with the American National Standard Method for Measuring Performance of Portable Household Electric Cord-Connected room Air Cleaners (ANSI/AHAM AC-1) to determine the products' clean air delivery rate (CADR) for dust, smoke and pollen.

Bionaire's products also have been tested by Underwriters Laboratories Inc. (UL) and have been found to meet the safety requirements of relevant UL standards.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. Paul Crowhurst
Vice-President, Technology
Bionaire® Incorporated
2000 32e Avenue
Lachine, Quebec, Canada H8T 3H7

DEC 14 1994

Re: K942434
Trade Name: Bionaire Clean Air Purifier & Ionizer LP-
1500, F-70, F-100, F-150, F-250
Regulatory Class: II
Product Code: FRF
Dated: September 23, 1994
Received: September 26, 1994

Dear Mr. Crowhurst:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

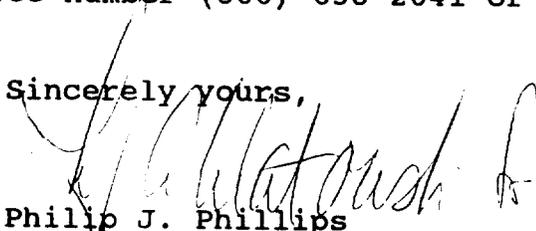
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device.

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Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Promotion and Advertising Policy Staff, (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Philip J. Phillips
Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health

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