DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Robert Kotler, M.D.
436 North Bedford Drive, #201
Beverly Hills, California 90210

SEP 1 3 2010

Re: K093454
Trade Name: Post-Op Nasal Airway System
Classification Regulation Name and Number: Nasopharyngeal Airway
21 CFR 868.5100
Regulatory Class: Class I Exempt
Product Code: BTQ
Dated: June 27, 2010
Received: June 29, 2010

Dear Dr. Kotler:

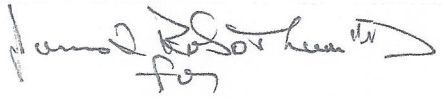
We have reviewed your premarket notification submission and have found this device to be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (Act). Therefore, you may immediately begin marketing this device as described in your premarket notification.

The final classification regulation for your device appears in Title 21 of the Code of Federal Regulations (CFR) 868.5100. We suggest that you review this regulation since it may grant other exemptions from certain general controls of the Act. Your device classification regulation name, regulatory class, and product code are shown above. When listing your device with the Food and Drug Administration, please use this product code.

In the future, new but substantially equivalent devices which fall within the above classification regulation name and meet the classification criteria may be marketed without sending a premarket notification submission to the Food and Drug Administration. We suggest, however, that you review 21 CFR Section 868.9 to determine whether or not your new device (s) meets the limitations of exemption from Section 510(k) of the Act.

If you have any questions regarding this letter, please contact Tam Cillie at (240) 796-6269 or the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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