



Santé Health
Canada Canada

LN/NH: 67656

Therapeutic Products Directorate
Medical Devices Bureau
Direction des produits thérapeutiques
Bureau des matériels médicaux

Medical Device Licence

Homologation d'un instrument médical

Licence Number:

67656

No d'homologation:

First Issue Date:

2005/03/08

Première date de délivrance:

Device Class/Classe de l'instrument: 2

This Licence is issued in accordance with the Medical Devices Regulations, Section 36, for the following medical device:

La présente homologation est délivrée en vertu de l'article 36 du Règlement sur les instruments médicaux pour l'instrument médical suivant:

Licence Name/Nom de l'homologation:

ANODYNE THERAPY SYSTEM

Manufacturer Name & Address/Nom du fabricant & adresse

ANODYNE THERAPY, LLC

13570 WRIGHT CIRCLE
TAMPA, FLORIDA
UNITED STATES
33626

R.G. Rottler, Ph.D., Director, Medical Devices Bureau/Directeur, Bureau des matériels médicaux

Application Number:

90269

Numéro de la demande:

Manufacturer ID:

Identificateur du fabricant:

121164



Components/Parts/Accessories/Devices for this Licence
Les composantes, parties, accessoires et instruments médicaux pour cette homologation

ANODYNE THERAPY SYSTEM

Device ID/No de l'instrument: 210895

Model/Catalog Detail/No de modèle/Catalogue:

MODEL 120

MODEL 480

ANODYNE THERAPY PADS

Device ID/No de l'instrument: 210896

Model/Catalog Detail/No de modèle/Catalogue:

498501



APPLICATION FOR A NEW CLASS II MEDICAL DEVICE LICENCE (disponible en français)

10. **PURPOSE/INTENDED USE:**

A description of the medical conditions, purposes and uses for which the device is manufactured, sold or represented: *[Note: Failure to supply an appropriate level of detail may result in the application being rejected.]*

Temporarily increases local circulation and reduces pain.
Temporarily reduces disturbances of skin sensation due to diabetic and other peripheral neuropathies
Used adjunctively with physical therapy, temporarily increases balance and reduces fall risk of patients with diabetic and other peripheral neuropathies.