

Medical Device Registration/Listing:

USA FDA:

Manufacturer's Establishment Number: 3003959465

Initial Distributor:

Triodent Corporation
35A The Commons
3524 Silverside Road
Edgemoor
Delaware, 19810
USA
Establishment Number: 3005486632

FDA Device Listing: Class 1 Devices

UK/CE:

Reference Number: CA009769
Manufacturer of Class 1 Medical Devices.

Authorised Representative:

Triodent (UK) Limited
1st Floor
64 Baker Street
London
W1U 7GB

Canada:

Class 1 Medical Device Manufacturer - Establishment Licence Number: 2658

New Zealand MEDSAFE:

All devices listed on WAND database as Class 1 Medical Devices

Australia TGA:

All devices are included on the ARTG (Australian Register of Therapeutic Goods) as Class 1 Medical Devices

Harmonized Customs Code: HS 9018.49