



76 W. 13775 S. Unit 4
Draper, UT 84020
1-877-938-7554

Proprietary Names: FuseRight by FootScientific
FDA Registration: 3008777042
PIN: 50042719
PCN: 11150913
Operation Number: 10034743
Regulatory Class: 1
Class Registration: 510(K) Exempt
Listing Number: D364519
Registered Code: HTO
Registration Date: December 9th, 2019 12:39 PM MT

As of December 09, 2019 a registration with the FDA was approved/Renewed for Fuse Right by FootScientific, Inc. It is registered as a class 1 device HTO reamer. As a class 1 device Fuse Right is a pre market approved 510k exempt product with an approved registration number of 3008777042.

FDA registration is not an endorsement, or a certification. Responsibility remains to ensure compliance to all marketing, sterilization, and manufacturing procedures. A regulatory class number 1 has its own limitations refer to the code of Federal Regulations (CFR, and in the Federal Register. Marketing the device is subject to general controls provisions included yearly registration, description of device, controlled manufacturing, packaging, and limits for branding concerning packaging.