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Establishment Registration & Device Listing

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| | |
|---|--|
| Proprietary Name: | Edge File; Smart Track File |
| Classification Name: | FILE, PULP CANAL, ENDODONTIC |
| Product Code: | EKS ⁶ |
| Device Class: | 1 |
| Regulation Number: | 872.4565 ⁷ |
| Medical Specialty: | Dental |
| Registered Establishment Name: | US Endodontics, LLC ⁸ |
| Registered Establishment Number: | 3008857765 |
| Owner/Operator: | US Endodontics, LLC ⁹ |
| Owner/Operator Number: | 10035363 |
| Establishment Operations: | Contract Manufacturer |

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1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
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3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/MedicalDevices/default.htm>
5. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>
6. [../cfPCD/classification.cfm?ID=1154](http://www.fda.gov/cfPCD/classification.cfm?ID=1154)
7. [../cfCFR/CFRsearch.cfm?FR=872.4565](http://www.fda.gov/cfCFR/CFRsearch.cfm?FR=872.4565)
8. [../cfRL/rl.cfm?rid=126315](http://www.fda.gov/cfRL/rl.cfm?rid=126315)
9. [../cfRL/rl.cfm?start_search=1&OwnerOperatorNumber=10035363](http://www.fda.gov/cfRL/rl.cfm?start_search=1&OwnerOperatorNumber=10035363)

Page Last Updated: 03/30/2015

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