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**PIONEER LABORATORIES**  
**510(K) NOTIFICATION SUMMARY**  
*for*  
**GTR (Greater Trochanteric Reattachment) DEVICE**

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**ADMINISTRATIVE INFORMATION**

**Manufacturer Identification and Sponsor:**

Pioneer Laboratories  
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Marquette, MI 49855  
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**Official Contact:**

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**DEVICE IDENTIFICATION**

**Proprietary Name:**

Pioneer System GTR (Greater Trochanter Reattachment) Device

**Classification Name:**

Cerclage, Bone Fixation CFR 888.3010

**Device on which substantial equivalence is claimed:**

Dall-Miles Trochanter Cable Grip manufactured by Howmedica

## **DEVICE DESCRIPTION**

The Pioneer Greater trochanteric Reattachment Device (GTR) is a low profile, ovaloid stabilizer combined with multifilament cables. The cables are affixed to the ovaloid stabilizer and serve to attach the device to the trochanter providing fixation. Instruments that tension and lock the cable are provided with the GTR system. The GTR is offered in two (2) styles.

The GTR stabilizer is designed with proximal fingers which hook over the top of the proximal osteotomized trochanter and serve to position the device during fixation and apply a distal force after fixation. The extended version incorporates a distal plate stem.

The cables are affixed to the GTR unit are passed around or through the femur and back into the GTR Device. The ovaloid GTR unit is placed on the osteotomized trochanter which is then positioned on the femur. Proper tensioning is applied to the cables with a tensioning instrument. The cables are then locked in place by tightening a screw which crimps a sleeve and cable.

## **INTENDED USE**

The GTR Device is used for the reattachment of the greater trochanter following osteotomy in total hip arthroplasty. Additionally, the device is used to reattach the greater trochanter following fracture of the greater trochanter.

## **SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO PREDICATE DEVICE**

Both devices utilize cable which holds the device and anchors the trochanter. The cables are crimped into place. The Dall-Miles device utilizes a crimping tool whereas the Pioneer device uses a screw.

The Dall-Miles device is H-shaped whereas the Pioneer device is oval. Both use proximal hooks for the top of the osteotomized trochanter. Both offer cobalt chrome cable. The Pioneer device is made of titanium--the Dall-Miles cobalt chrome.

**PERFORMANCE DATA**

The Pioneer Laboratories device was predicated on the use of stainless steel wire and the Dall-Miles Cable Grip System. All three systems were tested in static and fatigue loadings. Both the Pioneer and Dall-Miles Greater Trochanteric Reattachment Devices exceeded the static and fatigue values obtained by wire systems. Additionally, values obtained indicate the Pioneer GTR equaled or was greater than Dall-Miles.