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**Class 2 Device Recall DRAD SelfTapping Locking Screw**

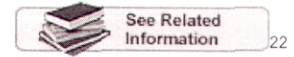


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**Class 2 Device Recall DRAD SelfTapping Locking Screw**



<b>Date Initiated by Firm</b>	March 07, 2018
<b>Date Posted</b>	March 20, 2018
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-1317-2018
<b>Recall Event ID</b>	<a href="#">79515</a> <sup>23</sup>
<b>510(K)Number</b>	<a href="#">K132296</a> <sup>24</sup>
<b>Product Classification</b>	<a href="#">Screw, fixation, bone</a> <sup>25</sup> - <b>Product Code</b> <a href="#">HWC</a> <sup>26</sup>
<b>Product</b>	D-RAD Self-Tapping Locking Screw intended for the fixation of fractures involving the distal radius. smith&nephew D-RAD 2.4MM X 10MM S-T LOCKING SCREW, REF 74692410, QTY (1), STERILE R
<b>Code Information</b>	Lot Number 17GM04522
<b>Recalling Firm/Manufacturer</b>	Smith & Nephew, Inc. 1450 E Brooks Rd Memphis TN 38116-1804
<b>For Additional Information Contact</b>	David Snyder 978-749-1440
<b>Manufacturer Reason for Recall</b>	One lot of D-RAD Self-Taping Locking Screws used with the Distal Radius Fracture Kit were machined out of specification. Screws measured over tolerance within the head thread form by 0.002-0.003 inch.
<b>FDA Determined Cause<sup>2</sup></b>	Under Investigation by firm
<b>Action</b>	The firm initiated their recall by letter and email on 03/07/2018. The firm requested return of the product.
<b>Quantity in Commerce</b>	59 units
<b>Distribution</b>	US, Puerto Rico, Malaysia
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report</a> <sup>27</sup>

<sup>1</sup> A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about [medical device recalls](#)<sup>28</sup>.

<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

<sup>3</sup> The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

**510(K) Database**      [510\(K\)s with Product Code = HWC and Original Applicant = SMITH & NEPHEW, INC.](#)<sup>29</sup>