Food and Drug Administration (FDA) Authorization of Novel Orthopaedic Devices with Pediatric Indications

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INTRODUCTION:

Medical device innovation is instrumental to improving the daily lives of patients. Pediatric patients represent a unique population for orthopaedic device development secondary to their size, growth, development, body chemistry, and disease propensity. Many surgeons express concern that an “innovation gap” (lower rates of medical device development) exists for pediatric orthopaedics compared to the orthopaedic specialty as a whole, but there is little literature quantifying its extent. In 2014, the FDA estimated that pediatric device development experiences a “lag” of 5 to 10 years compared to adult device development; as a result, some orthopaedic surgeons repurpose or modify devices for off-label use in children. Furthermore, resources to devise potentially innovative technologies targeting pediatric specific conditions are lagging despite passage of the 2007 Pediatric Medical Device Safety and Improvement Act meant to stimulate development.

To our knowledge, this is the first study to analyze orthopaedic devices authorized by the FDA for approved use in the pediatric population. We hypothesized, proportionally, the number of devices primarily indicated for use in pediatrics is substantially lower than the numbers approved for the adult population in orthopaedics.

METHODS:

Depending on device novelty and perceived risk, the FDA uses 4 pathways for authorization: PMA, 510(k), De Novo; and Humanitarian Device Exception (HDE). From the FDA website, files containing information on all authorized orthopaedic devices from each pathway, including manufacturer’s name, date of approval, and unique identification number were downloaded. This is a publicly available database. Searching the FDA website by identification number located approval summaries stating indications for use for each device. Devices with indications for pediatric use were recorded as “Pediatrics Only” or “Both Pediatrics and Adult.” Per FDA guidelines, devices with pediatric indications were classified as: infant (0-2), toddler (2-12), and/or adolescent (12-17). Primary subspecialty (Spine, Trauma, etc.) were recorded, as well as device company and date of approval. For PMA, HDE, and De Novo, every device approved since their creation (1976, 1990, and 1997, respectively) until 12/31/2022 were included. The 510(k) devices were limited to clearance dates between 01/01/2018 - 12/31/2022. Devices approved via “Special 510(k)” were excluded because this pathway is designed for only modifications to existing 510(k) devices. Devices without approval summaries were also excluded.

Analysis of each FDA pathway is important because each is purposed with assessing different types of devices. The 510(k) devices are “moderate risk” and must show “substantial equivalence” to an already marketed device, but do not need clinical data. PMA devices are “highest risk” and must undergo clinical trials to prove “safety and effectiveness.” HDE devices are also high-risk, but intended to treat diseases with <8,000 cases/year. They must supply clinical data, but require only proof of “probable benefit.” De Novo devices are determined to be moderate risk, but have no available equivalent devices. They must demonstrate a "reasonable assurance of safety and effectiveness."

RESULTS:

510(k): There were 1,926 devices cleared via 510(k) in the 5-year study period, of which 9 (0.5%) were exclusively pediatric. Of these, 5 were spine and 4 were trauma devices. There were 162 (8.4%) of devices indicated for both pediatrics and adults. Of these, 69 (42.6%) were for ages adolescent and older, while 65 (40.1%) provided no further age guidance in its indications.

PMA/HDE/De Novo: Since the inception of each pathway, there have been 76 PMA and 8 De Novo approved orthopaedic devices, none of which were indicated as primarily pediatric. Of the 11 approved HDE devices, 2 (18.2%) were for pediatric patients, and both were spinal devices. The one De Novo device indicated for both pediatrics and adults was a sports device limited to ages >14 years old, while the HDE device was for all ages.

DISCUSSION AND CONCLUSION:

This study found a disproportionately small number of devices being authorized for pediatric use through the various FDA pathways. Despite constituting 22% of the US population, less than 1% of novel devices have primarily pediatric indications. These are almost all cleared by showing “substantial equivalence” to an existing device via 510(k), a process not requiring clinical data. No PMA or De Novo orthopaedic devices have ever been approved with indications solely for pediatric patients. Greater awareness and further research into causes of this innovation gap are necessary.

Table 1: Orthopedic Device Approval by Age and Pathway

	FDA Approval Pathway			
Age Indications	510(k)	De Novo	PMA	HDE
Peds Only	9 (0.5%)	0	0	2 (18.2%)
Both	162 (8.4%)	1 (12.5%)	0	1 (9.1%)
Adult Only	1755 (91.1%)	7 (87.5%)	76 (100%)	8 (72.7%)
Total	1926	8	76	11