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Comment to FDA new Strategy on reuse of  
Single - Use Medical Devices.

I represent ORTHO CYCLE CO., INC. We provide a service to Orthodontists. We process used, direct bonding, stainless steel ORTHODONTIC BRACES, which are medical devices class I, non sterile, premarket requirements exempt. In the treatment, the devices are affixed to teeth with an adhesive. When the treatment is finished the braces are removed along with the polymerized glue.

In order to reuse the braces one has to remove the adhesive. We did not invent the reuse of orthodontic braces: for many many years it was done "in house" by the orthodontist or his "girls".

With the boom of orthodontic "american smiles" and the more and more sophisticated appliances came the need for professionals. We are one of them. In the last 24 years Ortho Cycle has developed and constantly improved procedures to clean small stainless steel appliances without changing the metal's structure. While removing the adhesive our cleaning system destroys any living organism. Once the cleaning/decontamination was achieved we start checking the DEVICE INTEGRITY. Under various magnifications the devices are measured and visually inspected five times. The reusable appliances are separated from the damaged one which we do not reconstruct or repair. We also separate the "lemons"- devices which have obvious mechanical defects "passed" by the original manufacturer.

The orthodontic braces are "non sterile" devices but we go overboard and autoclave them just before packing and mailing breaking the contamination chain, between our employees and the orthodontic office this time. Many years ago and by many organizations, the appliances we process were found "substantially equivalent to the legally marketed predicated devices".

Obviously, due to the specifics of the devices we are cleaning, we now deal with very large numbers and we are not the only ones in the business. The result is a self protective, united action of our OEM's (original equipment manufacturer): The reuse of orthodontic braces

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being so spread, the manufacturers declared them... disposable, "for single use only". Why? Is the quality of the new stainless steel braces poorer than, let say, five years ago? If so, the manufacturers should admit it on the label, along with the explanation for "single use only" and the restriction of the resale licence.

We think that the stainless steel orthodontic braces should be categorized as LOW RISK, REUSABLE DEVICES.

We agree with FDA's strategy that the processing should comply with Good Manufacturing Practices. Ortho Cycle is registered as a medical device manufacturer since 1991 and in the process of obtaining ISO 9002 certification.

We make a continuous research effort to deepen the knowledge of the appliances we are cleaning, the composition and behavior of the metal used as well as the effect of wearing on the device. Quarterly we publish our findings in our newsletter "Insider" distributed free to thousands of orthodontists. Our president, Dr. Claude Matasa teaches biomaterials in a few universities around the country and the world.

*Presented on Dec. 14. 99*

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