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March 28, 2005

Via Registered Mail

Division of Dockets Management,
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Request for Advisory Opinion

We represent Great Lakes Orthodontics, Ltd. ("Great Lakes"). The undersigned, on behalf of Great Lakes, submits this request for an advisory opinion of the Commissioner of Food and Drugs with respect to whether, under the circumstances described below, a manufacturer and seller is required to have a 510(k) for a medical or dental device for which a 510(k) is otherwise required.

A. Issues Involved.

May an entity that does not have its own 510(k) (either a 510(k) it procured itself or a 510(k) properly assigned to it) manufacture and sell under its own name a medical or dental device for which a 510(k) is required? If not, can an entity that does not hold a 510(k) avoid the prohibition if it indicates in the labeling the name of the entity that does hold the 510(k) for the device?

B. Statement of Facts and Law.

Assume that Company A obtains a 510(k) for its dental or medical device (the "Device"). Company A retains its 510(k). However, for a fee, Company A allows Companies B, C and D to manufacture and sell the Device under their own names. Companies B, C and D do not have their own 510(k)s for the Device.

Neither Companies B nor C indicate in their labeling for the Device that Company A holds a 510(k) for the Device. Company D, while still manufacturing and selling under its own name, states in its labeling that Company A holds the 510(k) for the Device.

Can Companies B and C manufacture and sell the Device as described? If not, does the labeling that Company D uses allow it to manufacture and sell the Device?

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Assume that a 510(k) is required for the Device and that the Device is being sold by each of the manufacturers in finished form under their own names. 21 C.F.R. §807.81 requires "each person" who intends to introduce a device into interstate commerce or commercial distribution to submit a pre-market notification. Further, 21 C.F.R. §807.85(b) exempts "distributors" from having to obtain a 510(k) if, among other things, the distributor does not "otherwise affect the device." The exemption for distributors, though, does not seem to extend to an entity that manufactures and sells.

The undersigned certifies that, to the best of his/her knowledge and belief, this request includes all data, information, and views relevant to the matter, whether favorable or unfavorable to the position of the undersigned, which is the subject of the request.

Thank you for your attention to this matter.

Signature: _____

Legal Counsel Making Request:
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