LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.

JAMES R. PHELPS
PAUL M. HYMAN
ROBERT A. DORMER
STEPHEN H. McNAMARA
ROGER C. THIES
THOMAS SCARLETT
JEFFREY N. GIBBS
BRIAN J. DONATO
FRANK J. SASINOWSKI
DIANE B. McCOLL
A. WES SIEGNER, JR.
ALAN M. KIRSCHENBAUM
DOUGLAS B. FARQUHAR
JOHN A. GILBERT, JR.
JOHN R. FLEDER
MARC H. SHAPIRO

ROBERT T. ANGAROLA
(1945-1996)

DIRECT DIAL (202) 737-4282

700 THIRTEENTH STREET, N.W.
SUITE 1200
WASHINGTON, D. C. 20005-5929
(202) 737-5600
FACSIMILE
(202) 737-9329

www.hpm.com

SAMIA N. RODRIGUEZ
MARY KATE WHALEN
OF COUNSEL

JENNIFER B. DAVIS
FRANCES K. WU
DAVID B. CLISSOLD
KATE DUFFY MAZAN
HOLLY M. BAYNE
CASSANDRA A. SOLTIS
JOSEPHINE M. TORRENTE
MICHELLE L. BUTLER
PATRICIA A.A. VANSTORY
THOMAS R. GIBSON
LEIGH E. KENNEDY*
ANNE MARIE MURPHY*
PAUL L. FERRARI
JEFFREY N. WASSERSTEIN
BRIAN J. MALKIN

*NOT ADMITTED IN DC

May 15, 2001

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
12420 Parklawn Drive
Room I-23
Rockville, Maryland 20857

Re: Docket No. 00P-1535

Dear Sir or Madam:

On September 22, 2000 Boston Scientific Corporation (Boston Scientific) submitted a petition under 21 C.F.R. §§ 10.25 and 10.30 requesting that the Commissioner of Food and Drugs amend 21 C.F.R. § 876.1075(b)(2) to limit the exemption from premarket notification requirements so that it would apply only to reusable biopsy forceps and non-reprocessed single use biopsy forceps. Boston Scientific has not yet received any response from the Food and Drug Administration (FDA or Agency) regarding this petition. FDA's regulations state that the "Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition."[1] On behalf of Boston Scientific, we respectfully request that FDA issue a prompt response.

[1] 21 C.F.R. § 10.30(e)(2).

2603 MAIN STREET
SUITE 650
IRVINE, CALIFORNIA 92614
(949) 553-7400
FAX: (949) 553-7433

4819 EMPEROR BOULEVARD
SUITE 400
DURHAM, NORTH CAROLINA 27703
(919) 313-4750
FAX: (919) 313-4751

As FDA has recognized, reprocessed single use biopsy forceps are "high risk" devices because of the potential for infection or functional failure due to reprocessing.[2] Despite this risk assessment, reprocessed single use biopsy forceps currently escape FDA's premarket requirements because they are regulated under 21 C.F.R. § 876.1075(b)(2) which exempts biopsy forceps from premarket requirements. Recognizing the potential for certain high risk reprocessed devices to escape premarket review because of exemptions granted to their new device counterparts, FDA committed to review the classification regulations for such devices on a case-by-case basis.[3] Boston Scientific's petition provides FDA with its first opportunity to review and address such a regulation.

The petition and October 24, 2000 supplement submitted to this docket by Boston Scientific contain extensive data which demonstrate reprocessing failure with these devices. Devices tested by Boston Scientific and found non-sterile were taken from hospital stocks and would have been used in patients if not for this testing. Premarket review of reprocessed single use biopsy forceps is critical to ensuring the safety of these devices.

In light of the importance of this issue and the passing of FDA's 180-day deadline for responding to the petition, we hereby request a prompt response approving or denying the petition.

Respectfully submitted,

Robert A. Dormer

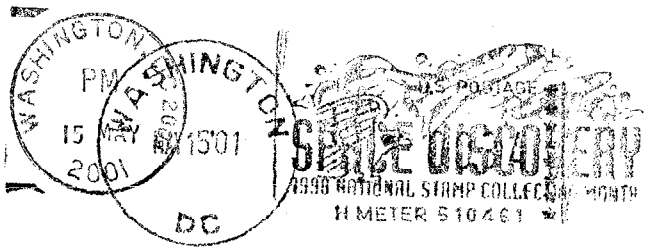
RAD/dmh

---

2 FDA Draft Guidance, Single-Use Devices, Reprocessing and Reuse: Review Prioritization Scheme (Feb. 8, 2000).

3 FDA Guidance, Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals (Aug. 14, 2000).

HYMAN, PHELPS & MCNAMARA, P. C.
700 THIRTEENTH STREET, N. W.
SUITE 1200
WASHINGTON, D. C. 20005



HFA
305

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
12420 Parklawn Drive
Room I-23
Rockville, Maryland 20857